

## **REDACTED DOCUMENTS RELATED TO DOCKET 8186**

### **8186-Plaintiffs' Omnibus Separate Statement of Facts in Support of Their Response to Defendants' Motion for Summary Judgment in the Bellwether Cases – Filed Redacted**

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|---------------------|---|
| <b>Exhibit H-A:</b> | <b>Selected Medical Records of Lisa Ann Hyde;</b>                 |
| <b>Exhibit H-B:</b> | <b>Excerpts of 4/6/17 Deposition of David Henry, M.D.;</b>        |
| <b>Exhibit H-C:</b> | <b>Excerpts of 1/25/17 Deposition of Lisa A. Hyde;</b>            |
| <b>Exhibit H-D:</b> | <b>Lisa A. Hyde Fact Sheet;</b>                                   |
| <b>Exhibit H-E:</b> | <b>Excerpts of 3/23/17 Deposition of William T. Kuo, M.D.;</b>    |
| <b>Exhibit H-F:</b> | <b>Excerpts of 7/6/17 Deposition of Robert McMeeking;</b>         |
| <b>Exhibit J-A:</b> | <b>Selected Medical Records of Doris Jones;</b>                   |
| <b>Exhibit J-B:</b> | <b>Excerpts of 3/23/17 Deposition of Anthony Avino, M.D.;</b>     |
| <b>Exhibit J-C:</b> | <b>Doris Jones Consent Form dated 8/23/10;</b>                    |
| <b>Exhibit J-I:</b> | <b>Excerpts of 8/5/17 Deposition of David Chodos, M.D.;</b>       |
| <b>Exhibit J-J:</b> | <b>Excerpts of 3/23/17 Deposition of Kirstin Nelson, M.D.;</b>    |
| <b>Exhibit J-Q:</b> | <b>Excerpts of 7/18/17 Deposition of Mark W. Moritz, M.D.;</b>    |
| <b>Exhibit M-A:</b> | <b>Selected Medical Records of Debra Mulkey;</b>                  |
| <b>Exhibit M-C:</b> | <b>Excerpts of 4/11/17 Deposition of Roderick Tompkins, M.D.;</b> |
| <b>Exhibit M-D:</b> | <b>Excerpts of 2/8/17 Deposition of Debra Mulkey;</b>             |
| <b>Exhibit M-E:</b> | <b>Debra Mulkey Fact Sheet;</b>                                   |
| <b>Exhibit M-I:</b> | <b>Excerpts of 6/1/17 Deposition of Pho M. Nguyen, M.D.</b>       |

**8186-Plaintiffs' Omnibus Separate Statement of Facts  
in Support of Their Response to Defendants' Motion  
for Summary Judgment in the Bellwether Cases –  
Filed Redacted**

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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products  
Liability Litigation

No. MD-15-02641-PHX-DGC

**PLAINTIFFS' OMNIBUS SEPARATE  
STATEMENT OF FACTS IN  
SUPPORT OF THEIR RESPONSE TO  
DEFENDANTS' MOTION FOR  
SUMMARY JUDGMENT IN THE  
BELLWETHER CASES**

Plaintiffs submit this Omnibus Separate Statement of Facts in Support of their  
Response to Defendants' Motion for Summary Judgment in the bellwether cases.

**I. FACTS COMMON TO ALL CASES**

**A. Bard Departs from A Proven IVC Filter to Make More Money.**

1. Beginning on approximately April 28, 1995, Bard Peripheral Vascular, Inc. ("BPV") and C.R. Bard, Inc. ("C.R. Bard") (collectively "Bard") manufactured and sold an inferior vena cava ("IVC") filter called the Simon Nitinol Filter ("SNF"). *See* 510(k) Premarket Notification, FDA website, *available at* <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K944353> (last accessed Oct. 2, 2017). Bard marketed the SNF as a device to be implanted in a patient's IVC to trap blood clots to prevent the clots from traveling to the heart and lungs and potentially causing a pulmonary embolism ("PE"). US FDA Clinical Data Summary of the Simon Nitinol Filter, attached as Exhibit 1, BPVE-01-00280772, at 73; Ex. 8, BPVE-01-00066044.

1           2.       The basic performance specifications for Bard IVC filters were that the  
2 devices must not migrate, require hook strength for stability and migration resistance,  
3 should not break or come apart during their lifetime, and must not fracture as result of  
4 corrosion or stresses within the body. Deposition of John McDermott, Feb. 5, 2014,  
5 attached as Exhibit 2, at 83:9-92:18; Product Performance Specification Recovery Filter  
6 and Femoral Delivery System, Nov. 2003, attached as Exhibit 3, BPVE-01-00010390-  
7 416, at 403.

8           3.       The SNF filter largely met these design and patient safety goals, performing  
9 very well in patients. Email from David Ciavarella to Brian Barry and Chris Ganser re G2  
10 Caudal Migrations, Dec. 27, 2005, attached as Exhibit 4, BPVE-01-00028224-25.

11           4.       The Simon Nitinol Filter had only 8 fractures out of sales of 80,187 between  
12 launch and May 2011. Chart of Filter Fracture Complaints, attached as Exhibit 5,  
13 BPVEFILTER-01-00037664. As the predicate device for Recovery, this is the standard of  
14 performance against which the Recovery filter is measured for substantial equivalence and  
15 safety and effectiveness. Deposition of Donna B. Tillman, June 12, 2014, attached as  
16 Exhibit 6, at 101:20-23, 115:23-116:3, 119:23-120; Deposition of Christine Brauer, dated  
17 Aug. 2, 2017, attached as Exhibit 7, at 202:19-203:8.

18           5.       Early clinical studies demonstrated that migration of the SNF filter device  
19 was rare, with only 2 of 258, or 0.8%, migrations reported for patients who received the  
20 SNF between February 1988 and November 1990, while there were no reports of filter  
21 fractures observed. Ex. 1, BPVE-01-00280772, at 72, 86; Simon Nitinol Filter/Straight  
22 Line Technical File, attached as Exhibit 8, BPVE-01-00066044-109, at 98-99. Since  
23 these early clinical studies there have been zero SNF migration deaths and a significantly  
24 lower number of SNF migrations compared to Recovery, G2, and Eclipse reported to Bard  
25 through May 2011, Ex. 5, BPVEFILTER-01-00037664.

26           6.       Bard wanted to increase its market share in the IVC filter market and  
27 believed that developing a retrievable IVC filter would enable it to do so. Product  
28



1 Opportunity Appraisal for Recovery Filter System, Mar. 28, 2003, attached as Exhibit 9,  
2 BPV-17-01-00030247, at 249.

3 7. Officers at Bard recognized that modifying the design to allow for optional  
4 retrieval had the potential to significantly increase BARD's market share of the IVC filter  
5 market. *Id.*

6 **B. The Recovery Filter.**

7 8. The Recovery Nitinol Filter ("Recovery" or "RNF"), Bard's first "Optional  
8 Filter," was designed as a "permanent filter that you can remove long-term (12 weeks)"  
9 which was to have the "same strengths as permanent filters" with "arms designed for  
10 centering and caudal migration resistance," one (vena cava) size fits all (up to 28 mm),"  
11 "hooks (to) provide migration resistance when the filter is fully occluded," and would  
12 "convert to a permanent filter" if not removed within 12 weeks. NMT Cprdos  
13 presentation, June 14, 2000, attached as Exhibit 10, BPVE-01-00001342.

14 9. In April 2000, Dr. Murray Asch, an Interventional Radiologist from Canada,  
15 began his RNF retrievability study. Deposition of Murray R. Asch, May 2, 2016, attached  
16 as Exhibit 11, at 12:14-24; Murray R. Asch, MD, FRCPC, *Initial Experience in Humans*  
17 *with a New Retrievable IVC Filter*, Radiology 2002; 225:835-844 ("Asch Study Article"),  
18 attached as Exhibit 12. Thirty-four patients who needed IVC filters were selected to  
19 receive an RNF between April 2000 and November 2001. When Dr. Asch's first article  
20 regarding the study was published, 16 men and 16 women aged 18-83 years had been  
21 implanted with the RNF (2 patients of the original 34 selected were found to have  
22 anatomic conditions unfavorable for filter placement). *Id.* at 835, 837. The indications  
23 for placement were recent deep venous thrombosis, recent pulmonary embolism, and/or  
24 prophylaxis. *Id.* The mean implantation period was 53 days and the range was 5 to 134  
25 days. *Id.* at 835.

26 10. During Dr. Asch's treatment of the initial 32 patients, his test subjects  
27 encountered several complications with the RNF: 1 migration, 2 fractures, 2 tilts, 1  
28

1 perforation, and 19 deployment-related problems. Ex. 11, Asch Dep., at 26:8-15; Ex. 12,  
2 Asch Study Article, at 839-40 (tilts and deployment issues), 843 (perforation).

3 11. The Canadian Institutional Review Board (IRB) suspended the study after  
4 the filter fractures were reported. Email from George Cavagnaro to Doug Uelmen and  
5 Carol Vierling, April 18, 2002, attached as Exhibit 13, BPV-17-01-00052621 (forwarding  
6 email from Dr. Asch stating he had reported RNF fracture to the IRB and “the IRB has  
7 suspended the trial effective immediately until the nature of the problem with the device  
8 can be better understood”).

9 12. Dr. Asch testified that his study should never have been used to seek market  
10 clearance of the RNF in the U.S. Ex. 11, Asch Dep. at 23:7-24:19; 195:14-24.

11 13. Bard was aware of the Recovery filter’s design flaws and told Dr. Asch it  
12 would change the design or manufacturing process of the filter to try to prevent fractures.  
13 Bard admitted that pre-marketing fractures were likely due to weakness at the site of the  
14 weld, and that it was aware that it needed to increase robustness of the filter by designing  
15 it with larger diameter metal. Ex. 11, Asch Dep., at 40:19-41:11.

16 14. Defendants’ expert Dr. Donna B. Tillman testified that Bard had an  
17 obligation to assure that (a) “the device continues to be safe and effective and that they  
18 [sic] meets FDA’s quality system requirements throughout the life of the device,” (b)  
19 “[a]ssessed overall, the safety and effectiveness of the device could not be worse than the  
20 predicate device;” and (c) “[the device] needs to be as safe and effective as the predicate  
21 device.” Ex. 6, at 101:20-23, 115:23-116:3, 119:23-120:7.

22 15. On July 10, 2002, Bard submitted a special 510(k) application (K022236)  
23 modifying the SNF (the predicate device to which the filter was to be substantially  
24 equivalent) seeking clearance for a new IVC filter that would be known as the Recovery  
25 Filter. See [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K022236)  
26 [pmn.cfm?ID=K022236](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K022236); Letter from K. Fuller and C. Vierling to Food and Drug  
27 Administration, dated July 10, 2002, attached as Exhibit 14, BPV-17-01-00057953;  
28

1 Recovery Filter System Special 510(k) Submission, July 10, 2002, attached as Exhibit 15,  
2 BPV-TRIAL-EXHIBIT-0293.

3 16. If an IVC filter is cleared to be marketed in the United States based on  
4 substantial equivalence to an appropriate predicate device, there is an expectation that the  
5 new device will continue to be as safe and effective as the predicate device, post-  
6 marketing in the real clinical world. Ex. 7, 2017 Brauer Dep. at 202:19-203:8.

7 17. On November 27, 2002, Bard obtained clearance from the FDA to market  
8 the Recovery as a permanent IVC filter. Department of Health & Human Services letter,  
9 Nov. 27, 2002, attached as Exhibit 16, BPV-17-01-00057709.

10 18. Bard then bootstrapped this clearance to open the door for a retrievable  
11 filter. On April 25, 2003, Bard submitted an abbreviated 510(k) pre-market notification  
12 (K031328) in order to obtain an indication for retrievability for the RNF. Letter from  
13 Mary Edwards to FDA, Apr. 25, 2003, attached as Exhibit 17, BPV-17-01-00054947; *see*  
14 *also* [https://www.accessdata.fda.gov/cdrh\\_docs/pdf3/K031328.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf3/K031328.pdf) (last accessed Sept.  
15 25, 2017).

16 19. Bard's 510(k) applications for the RNF did not disclose that filters at the  
17 low end of the leg span set specification only met the migration resistance test when the  
18 hooks were engaged but that those hooks were not always engaged. Recovery Filter  
19 System Special 510(k) Submission (K022236), Nov. 27, 2002, BPV-17-01-00057953-55,  
20 attached as Exhibit 18; Ex. 15, Recovery Filter System Special 510(k) Submission, July  
21 10, 2002, BPV-TRIAL-EXHIBIT-0293.

22 20. Bard was aware that it had an "absence of solid clinical history" and  
23 "documented negative clinical experiences" for the RNF but was confident that those  
24 obstacles to selling the device could be overcome with "aggressive marketing." Product  
25 Opportunity Appraisal for Recovery Filter System, dated Mar. 28, 2003, BPV-17-01-  
26 00030247, Ex. 9, at 249.

1           21. In migration testing in 1999, NMT concluded that “the SNF filters were  
2 superior [to the Recovery] in 28 mm tubing.” R&D Technical Report, Aug. 5, 1999,  
3 attached as Exhibit 19, BPV-17-01-00002650, at 53.

4           22. To become a safer product, Recovery required longer arms, larger and  
5 stronger hooks by increasing diameter of the wire, and an increased leg span. Deposition  
6 of Robert Carr, Dec. 19, 2014, attached as Exhibit 20, at 120:20–122:1; Deposition of Len  
7 DeCant, May 24, 2016, attached as Exhibit 21, at 249:3-14.

8           23. Bard could have employed penetration limiters to improve perforations at  
9 the time the Recovery was designed and marketed, but did not do so for the Recovery.  
10 Transcript of deposition of Andrzej Chanduszek, Oct. 10, 2013, attached as Exhibit 22, at  
11 51:23–52:7.

12           24. Bard’s IFU for the Recovery Filter device does not include information for  
13 physicians that the device failed migration-resistance testing when the hooks were not  
14 engaged. Recovery Filter System for use in the Vena Cava, Information for Use, attached  
15 as Exhibit 23, BPVE-01-00435559; Deposition of David A. Kessler, M.D., attached as  
16 Exhibit 24, Oct. 5, 2016, at 179:3–181:19.

17           25. The failure of Recovery anchor hooks to engage was a marked difference  
18 from the SNF, eroding Bard’s claim that the device was substantially equivalent to the  
19 SNF. Ex. 24, Kessler Dep. at 179:3–181:19.

20           26. In ignorance of the design flaws in its product that Bard’s testing and  
21 experience had identified, FDA cleared the Recovery for a retrievability indication,  
22 allowing Bard to market the Recovery as a permanent filter with the option for retrieval  
23 on July 25, 2003. Department of Health & Human Services letter, dated July 25, 2003,  
24 attached as Exhibit 25, BPV-17-01-00058122-24.

25                   **1. The Recovery Quickly Proves Deadly.**

26           27. Bard began selling the Recovery filter to a limited market on December 20,  
27 2002; it had full market release in January 2004. Failure Investigations/R002 History  
28 Review, BPVEFILTER-01-00003802-836, attached as Exhibit 26, at 12 (limited); Special

1 Design Review for Recovery (Project #s 7081 and 8008) – Meeting Minutes, dated Dec.  
2 9, 2003, attached as Exhibit 27, BPVE-01-00407525-527, at 526 (full).

3 28. Starting in October of 2003, Bard began receiving complaints from real-  
4 world patients and physicians of migrations, fracture, and—starting in February 2004—  
5 deaths. Ex. 26, Failure Investigations/R002 History Review, at 12-14.

6 29. On December 9, 2003, less than a month prior to full market release of the  
7 Recovery filter, Bard did not have a full understanding of the design elements of the  
8 Recovery IVC filter. At that time, the Special Design Review team for the Recovery filter  
9 requested “objective evidence” of the following, among other things, (a) to document the  
10 criteria (50 mmHg) that Bard used for migration resistance; (b) a study that analyzed the  
11 filter’s migration resistance in conjunction with tilting and the number of legs/hooks  
12 secured; (c) a study that compared Recovery’s migration resistance to competitive  
13 products; (d) migration resistance of the Recovery with oval and/or D-shaped IVCs.  
14 Special Design Review for Recovery (Project #s 7081 and 8008) – Meeting Minutes,  
15 dated Dec. 9, 2003, Ex. 27, BPVE-01-00407525, at 26-27. Nonetheless, Bard chose not  
16 to conduct such studies prior to full market release of the Recovery. Ex. 21, DeCant Dep.  
17 at 195:22-196:19; 204:1-12; 204:22-205:6; 207:1-208:23.

18 30. Even after the commercial marketing of the Recovery filter began, Bard had  
19 many questions that needed to be answered about the performance of the device, but did  
20 know that it did not always stay centered in the vena cava even if properly deployed and  
21 centered. Email chain between Janet Hudnall to David Rausch, Feb. 26-27, 2004,  
22 attached as Exhibit 28, BPVE-01-00373887.

23 31. Bard learned of the first death from a Recovery filter migrating to the heart  
24 of a patient on February 9, 2004, approximately five weeks after full market release.  
25 Ex. 26, Failure Investigations/R002 History Review, at 12.

26 32. In a February 2004 email to Bard’s interventional sales force charged with  
27 communicating with the interventional radiology public, Bard communicated that testing  
28 of the Recovery showed that it performed “just as well as the SNF in terms of migration

1 resistance.” Email from Mary Edwards, February 13, 2004, attached as Exhibit 29, BPV-  
2 17-00164702-710, at 704.

3 33. At approximately the same time it was telling interventional radiologists that  
4 Recovery performed as well as the SNF with respect to migration resistance,

5 a. A February 25, 2004, internal test showed that the Recovery filter did not  
6 perform as well as the SNF in Bard’s migration resistance testing and in  
7 certain instances failed to meet its product performance specifications.

8 Email from Alex Tessmer to Robert Carr, Feb. 25, 2004, BPVE-01-  
9 00410985-1019, attached as Exhibit 30;

10 b. In a February 26, 2004, email between Bard employees Janet Hudnall and  
11 David Rausch Hudnall explained that “[w]e knew very little about the long-  
12 term clinical performance of this device when we launched it. After a year  
13 of commercialization, there are still many questions that need to be  
14 answered. One thing we do know, however, is that Recovery does not  
15 always stay centered in the cava. In fact, physicians will often find that it is  
16 tilted quite a bit when they go to retrieve it even though it seemed perfectly  
17 centered upon deployment.” Ex. 28, at BPVE-01-00373887;

18 c. Rausch agreed: “you are right; now that we have more experience with  
19 Recovery the positioning of tilt-resistance should probably be down  
20 played.” *Id.*

21 34. When Bard conducted migration-resistance testing comparing the Recovery  
22 filter against the SNF and competitive devices in March 2004, the Recovery performed  
23 worse than the SNF on every test, finished last or second to last among all tested devices  
24 on every test but one (on which it finished third to last), and failed Bard’s own standard  
25 for migration resistance on several tests. Characterization of Recovery Filter Migration  
26 Resistance in Comparison to Competitive Product Phase 1, BPVE-01-00276094, attached  
27 as Exhibit 31, at 97-99. Indeed, at the 28 millimeter IVC test, the Recovery had  
28 migrations at less than 50 mmHg; and at a temperature of 37 degrees Celsius (plus or

1 minus 2 degrees), the average resistance for the Recovery was 47.5 mmHg with a low  
2 resistance of 32.1 mmHg (well below Bard's threshold of 50 mmHg). *Id.* at 99.

3 35. This March 2004 testing further confirmed that the Recovery did not  
4 perform as well as the SNF in Bard's migration-resistance testing, and in certain  
5 instances, failed to meet its product performance specifications. Email from Alex  
6 Tessmer to Charlie Benware and others, Mar. 24, 2004, BPVE-01-00330122, attached as  
7 Exhibit 32.

8 36. Bard also knew the Recovery performed worse than competitor filters as  
9 well as the SNF. By March 25, 2004, based on migration resistance comparison testing  
10 between the Recovery and competitive filters, Bard reached the following conclusion:  
11 "[T]he migration resistance of the RNF appears comparable to the Gunther Tulip Filter  
12 throughout all simulated IVC diameters. The other filters Simon Nitinol Filter, Greenfield  
13 SF, Greenfield Ti, Optease and TrapEase seem to have a greater resistance to migration in  
14 comparison to the RNF and Gunther Tulip filter." Ex. 26, Failure Investigations/R002  
15 History Review, at 14; Engineering Test Report No. ETR-04-03-02, BPV-17-01-  
16 00001198-208, attached as Exhibit 33, at 208.

17 37. The head of Bard's Research & Development team, its Vice President of  
18 Research & Development, did not understand at the time of the March 2004 migration  
19 testing that the IVC can expand by 25 to 50 percent and, therefore, Bard's design did not  
20 take into account the IVC's real-world performance. Ex. 21, DeCant Dep. at 70:16-71:17,  
21 326:22-328:24.

22 38. According to Natalie Wong, Bard's Quality Engineering Manager for New  
23 Product Development, the Recovery was also worse than the SNF with regard to filter-  
24 related deaths and filter fracture. Deposition of Natalie Wong, Oct. 18, 2016, attached as  
25 Exhibit 34, at 77:10-78:12; 111:16-112:18. Nor was it as safe as competitor filters, since  
26 the Recovery had a higher rate of deaths and fractures. *Id.* at 77:16-78:12; 112:19-22.

27 39. Concerning the Recovery's performance against its 50 mmHg (50  
28 millimeters of mercury) standard, Bard's engineering staff observed "[y]ou will quickly



1 notice that there were values below 50.0 mmHG acceptance criteria for all three Starguide  
2 manufactured lots . . . .This points to the fact that there is an issue with the migration  
3 resistance testing.” Ex. 32, at BPVE-01-00330122.

4 40. In a Health Hazard Evaluation Bard acknowledged that in 50mmHG  
5 migration resistance testing the Recovery “had the lowest mean migration resistance” of  
6 all of the IVC filters evaluated. “Health Hazard Evaluation, dated Dec. 17, 2004, BPVE-  
7 01-01019821-25, attached as Exhibit 35, at 01019822.

8 41. On April 14, 2004, Bard learned of the second death from a Recovery filter  
9 migrating to the heart of a patient. Memo from Uelmen to Palermo dated June 11, 2004,  
10 BPV-17-01-00153581-88, attached as Exhibit 36, at 88. Following that death, Bard  
11 understood that the IVC could expand beyond its normal size. Ex. 21, DeCant Dep. at  
12 326:22-327:13. And, at that time, Bard understood that the Recovery was designed in a  
13 way that did not account for how the IVC actually behaved. *Id.* at 328:2-329:8.

14 42. On April 14, 2004, in light of this second death, the Recovery was placed on  
15 an internal “QA Hold” pending completion of a remedial action plan. Ex. 26, Failure  
16 Investigations/R002 History Review, at 14; Deposition of Chad Modra, Mar. 28, 2013,  
17 attached as Exhibit 37, at 181:1-19.

18 43. Physicians were not informed that Bard had placed an internal hold on the  
19 Recovery. Ex. 37, Modra Dep. at 183:9-12.

20 44. Rather than communicating its findings to the medical community, Bard  
21 created a “Crisis Communication Plan” which included hiring a public relations firm to  
22 handle the negative press if the situation with its failing retrievable filters were to be  
23 “exposed” in the media. *See* Crisis Communication Plan, BPV-17-01-00164733-164788,  
24 attached as Exhibit 38.

25 45. Bard’s messaging to the public was to be: “Bottom line: good filter, severe  
26 case, bad outcome, deep regret.” Bard determined that “[t] his [was] the simple story we  
27 should repeat again and again. Comparison with other filters is problematic in many ways,  
28 and we should avoid/downplay this as much as possible. When pressed, we [Bard] simply



1 paraphrase ... that estimates based on the available data suggest that there is no significant  
2 difference in the rates of these complications between any of the devices currently  
3 marketed in the U.S., including the Recovery device.” Email from John Lehman, April  
4 15, 2004, BPV-17-01-00165419, attached as Exhibit 39.

5 46. Bard described the situation with Recovery failures after the fact as so dire  
6 in the 2004-2005 time frame that it needed to be held together with “scotch tape, smoke,  
7 mirrors, crying etc.” Email from Jason Greer to Janet Hudnall, Mar. 16, 2006, BPVE-01-  
8 00946624, attached as Exhibit 40.

9 47. Despite Bard’s internal knowledge about the Recovery’s problems, the QA  
10 Hold was lifted on April 25, 2004, and Bard continued to sell the Recovery filter.  
11 Remedial Action Plan, April 21, 2004, BPV-17-01-00153578, attached as Exhibit 41, at  
12 153587.

13 48. In all, seven migration deaths associated with the RNF were reported  
14 between April and December 2004. (April 13, 2004, May 8, 2004; May 30, 2004; July 24,  
15 2004; August 16, 2004; November 15, 2004; November 28, 2004) Recovery Filter  
16 Detached Limbs—Patient Comparison Matrix dated November 1, 2005, BPV-17-01-  
17 00035618, attached as Exhibit 42, at 35615-39.

18 49. During this critical period, Bard knew that the Recovery:

- 19 a. had a fracture rate that was tens of times higher than other filters on the  
20 market. Health Hazard Evaluation, July 9, 2004, BPV-17-01-00002145  
21 attached as Exhibit 43.
- 22 b. was tilting in up to 30 percent of the implantations. Email chain with  
23 John McDermott, Len DeCant, and others, May 13, 2004, attached as  
24 Exhibit 44, BPVE-01-00036095-96, at 96.
- 25 c. was measurably less safe than the SNF and competitor devices as it  
26 related to death caused by: 1) migration 2) caval perforation 3) caval  
27 perforation 4) caval obstruction or 5) PE/acute respiratory event.  
28

1 Email from Natalie Wong to Doug Uelemen, May 20, 2004, BPV-01-  
2 00511127, attached as Exhibit 45.

3 d. had a significantly higher rate of complications from other filters  
4 including the SNF at “a 95% confidence.” *Id.* (stating that at “a 95%  
5 confidence, there IS a significant difference between Recovery,  
6 Gunther Tulip, Bird’s Nest and SNF.”).

7 50. Bard industry standards and regulatory expert Christine Brauer agreed that a  
8 reasonably prudent company should recognize and assume the enormity of a safety signal  
9 is *higher* than the actual rate derived from MAUDE and sales data rate analysis.  
10 However, Bard took no meaningful action to identify a root cause of failure or warn  
11 patients, physicians, or regulators about these deadly problems. Ex. 7, 2017 Brauer Dep.  
12 at 213:11-214:14.

13 51. Bard’s June 30, 2004 Health Hazard Evaluation reports “Migration of a  
14 thrombus-encased Recovery (IVC filter) has been reported in 10 patients” among 12  
15 migrations reported as of that date. Four of the 12 resulted in death to the patients. The  
16 author of the HHE, Dr. David Ciavarella, Bard’s Medical Director, further states, “The  
17 root cause of the thrombus-associated migration events is judged to be thrombus-induced  
18 pressure increase in the IVC, leading to acute IVC expansion beyond the design limits of  
19 the filter,” and as to one of the migrations he states “the ‘malfunction’ is best understood  
20 as a limitation of the ability of the device to carry out its intended function.” Updated  
21 Health Hazard Evaluation, June 30, 2004, attached as Exhibit 46, BPVEFILTER-  
22 01000014836-39, at 39.

23 52. Bard stated in an internal Frequently Asked Questions (FAQ) document  
24 about the Recovery that it was “rigorously tested for all physical performance  
25 characteristics according to [Bard’s] established test methods and protocols and was found  
26 to meet all test specifications and requirements.” Bard Recovery FAQ, July 15, 2004,  
27 BPVE-01-00268921-923, attached as Exhibit 47, at 923.  
28

1           53.     Less than two weeks later, on July 26, 2004, after the Recovery had been on  
2 the market for nearly a year, Len DeCant, Bard's Vice President of Research and  
3 Development, was told by his employee: "I think we should try to better quantify and  
4 understand how much these vessels expand if we are designing a device to anchor on/in  
5 the wall." Email from John McDermott to Len DeCant, July 26, 2004, BPV-DEP-  
6 00014246-247, attached as Exhibit 48, at 46. Moreover, Bard as of late August 2004 did  
7 not have reliable controlled clinical studies that "most educated individuals and physicians  
8 would accept as evidence [sic] of 'proof'. [sic] the safety and efficacy of the Recovery®  
9 Vena Cava Filter." Internal Q&A, Aug. 30, 2004, BPVE-01-00033810, attached as  
10 Exhibit 49, at 12.

11           54.     Despite its knowledge that the Recovery's overall complication rates were  
12 far greater than its competitor devices, Bard told the its employees in a "script" not to be  
13 deviated from, that Recovery complication rates were comparable to those reported in the  
14 literature and the MAUDE database for other IVC filters, including that migration was not  
15 occurring at an excess frequency with the Recovery when compared to competitor filters.  
16 *Id.* at BPVE-01-00033815; Ex. 47, at BPVE-01-00268921-23.

17           55.     Bard marketed the Recovery as a "marked improvement over currently  
18 available devices." 2004 Recovery Marketing Brochure, BPV-17-01-00007760-763,  
19 attached as Exhibit 50, at 7761. "Currently available devices" included the SNF and  
20 competitor filters at the time Recovery was launched into the market. Deposition of Jack  
21 Sullivan (Vols. I and II), Sept. 16, 2016 and November 3, 2016, attached as Exhibit 51  
22 and 84, at 80:16-81:12.

23           56.     By September 2, 2004, Bard was aware of 32 incidents of limbs fracturing  
24 on implanted Recovery filters. Remedial Action Plan, Sept. 2, 2004, BPV-17-01-  
25 00034860-887, attached as Exhibit 52. As a result, Bard instituted a Remedial Action  
26 Plan to address the problem of fractured arms. *Id.* But Bard concluded that there was "no  
27 single root cause for the reported limb detachments," so "no field remedial action [was]  
28 planned." *Id.* at 74.

1           57.     Bard's December 17, 2004, Health Hazard Evaluation stated, "An analysis  
2 of reporting rates of serious adverse events for all inferior vena cava filters, as determined  
3 by analysis of the MAUDE and IMS databases by a consultant, revealed that reporting  
4 rates for Recovery are significantly higher than other filters." Ex. 35 at BPVE-01-  
5 01019821. The HHE also noted that "[r]eports of death, filter migration (movement), IVC  
6 perforation, and filter fracture associated with Recovery filter were seen in the MAUDE  
7 database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than  
8 reporting rates for all filters. These differences were all statistically significant." *Id.* at  
9 22.

10           58.     Regarding the effectiveness of Bard's or any other IVC filter, Bard's  
11 Medical Director, Dr. David Ciavarella, stated in the HHE, "The existing literature is of  
12 poor quality, with insufficient randomized, controlled trials (RCT) to definitively establish  
13 the effectiveness of IVC filters." *Id.*

14           59.     On January 4, 2005, another Remedial Action Plan observed: "In the  
15 MAUDE dataset, the RNF demonstrated: a consistent, statistically significant and  
16 potentially clinically important higher rate of reporting adverse events in the several  
17 analyzed categories. . . . the data and [a consultant's] analysis provided two significant  
18 signals that further investigation particularly in relation to migration and fracture is  
19 urgently warranted. . . . Of greatest concern were reports of migration and fracture.  
20 Remedial Action Plan, January 4, 2005, attached as Exhibit 53, BPVE-01-01019773-825,  
21 at 19777-78.

22           60.     On April 19, 2005, Chris Ganser, Corporate V.P. of Regulatory Sciences  
23 and Head of Quality Assurance, reported to the CEO and COO of C.R. Bard comparative  
24 MAUDE/IMS data which was compiled by Bard for IVC filter fatalities, fractures and  
25 migrations (through Q4 2004) showing a higher rate of migration and fatalities with the  
26 Recovery versus the SNF and competitor filters. He also reported on a significantly  
27 greater number of fractures compared to SNF's 15 year marketing history. This data was  
28 from Bard's own internal adverse event reports and actual sales data and revealed the

1 following comparisons to the SNF which was Recovery's predicate device: 3300%  
2 greater rate of Recovery migrations (34 total); 14 deaths involving Recovery versus zero  
3 for SNF, including nine from migrations of the device to the heart and five from  
4 pulmonary emboli; and 51 Recovery fractures, 18 with metal struts embolizing to heart or  
5 lungs, and three requiring surgery to remove, including one open heart surgeries. Email  
6 from Chris Ganser to T. Ring, April 19, 2005, BPVE-01-00434275-76, attached as  
7 Exhibit 54.

8 61. By July 2005, Bard's sales force discussed internally that the SNF, the  
9 predicate to RNF, was the "safest filter on the market." Email from Jason Greer to Nicole  
10 Alpie and others, July 16, 2005, BPV-DEP-00005665-66, attached as Exhibit 55, at 66.

11 62. Chris Ganser again reported on August 3, 2005, to CR Bard CEO and COO,  
12 comparative MAUDE/IMS data for IVC filter fatalities, fractures and migrations  
13 compiled by Bard through the second quarter of 2005. The data showed a higher rate of  
14 migration and fatalities with the Recovery versus the SNF and competitor filters, and  
15 significantly greater number of fractures compared to SNF's 15-year sales history.  
16 Compared to the SNF, the data revealed: 4500% greater rate of Recovery migrations; 16  
17 deaths involving Recovery versus zero for SNF, including 11 from migrations of the  
18 device to the heart and five from pulmonary emboli the Recovery was intended to prevent;  
19 and 68 Recovery fractures, 25 with metal struts embolizing to heart or lungs and 4  
20 requiring surgery to remove. Executive Summary, August 3, 2005, BPV-17-01-  
21 00170083-84, attached as Exhibit 56.

22 **C. The G2 Filter.**

23 63. Bard then developed a next generation Recovery filter, known first as the  
24 "G1A improved recovery filter" and later as the "G2" filter, with the objective of  
25 addressing and minimizing problems of filter migration and filter arm fracture with the  
26 Recovery. Janet Hudnall, Avijit Mukherjee, and Robert Carr email chain, August 25-26,  
27 2004, attached as Exhibit 57, BPVE-01-00008821; Recovery Filter PowerPoint  
28 presentation, August 26, 2004, attached as Exhibit 58, BPVE-01-00009466-85, at 69-70.

1           64. Bard continued to sell the Recovery while it developed the G2. Email from  
2 Janet Hudnall to John McDermott, Feb. 11, 2005, attached as Exhibit 59, BPVE-01-  
3 00167251 (discussing options for “stock recovery/rotation” for Bard’s vena cava filters  
4 once G1A/G2 filter was cleared for sale); Failure Investigations/R002 History Review,  
5 attached as Exhibit 60, BPVEFILTER-01-00003802, at 11 (G2 project started 9/13/04;  
6 “9/2005 G2 is released, RNF is discontinued end of the month”).

7           65. The performance standard and predicate device for the G2 is the Recovery  
8 filter. Traditional 510(k) G2 Filter with Femoral Delivery, attached as Exhibit 61, at  
9 FDA\_PRODUCTION\_00000048-49, at 49.

10          66. There was a “statistically significant difference” between the performance of  
11 the G1A/G2 filter and that of the SNF in migration resistance testing when compared to  
12 the SNF. G1A Recovery Filter Femoral System Design Verification and Validation  
13 Report, attached as Exhibit 62, BPV-17-01-00001134-153, 46.

14          67. Bard’s labeling represented that the G2 Filter was safe and effective for  
15 permanent implantation in the human body for the prevention of pulmonary embolism.  
16 G2 Filter System Instructions for Use, attached as Exhibit 63, BPV-17-01-00137389-92,  
17 at 89.

18          68. Bard’s “Patient Questions & Answers” document for the G2 filter states that  
19 the G2 filter is designed to be a permanent implant and will not need to be removed,  
20 repositioned, or replaced. G2 Filter System, Patient & Answers, attached as Exhibit 64,  
21 BPV-17-01-00137624-32, at 29.

22          69. BARD represented in marketing materials including those distributed on the  
23 internet directly to patients that the G2 had increased migration resistance, improved  
24 centering, and enhanced fracture resistance. Marketing brochure for G2 Filter System for  
25 Permanent Placement, attached as Exhibit 65, BPV-17-01-00142912-15; Marketing  
26 Brochure for Recovery G2 Filter System, attached as Exhibit 66, BPV-17-01-00137588;  
27 *see also* 2005 G2 Filter-FAQs, attached as Exhibit 67, BPV-17-01-00062020-22, at 22  
28

1 (G2 Filter System was “more robust design” and represents Bard’s “best technology”  
2 offered to its customers).

3 70. Bard expert witness Dr. Brauer testified that documents like those cited in  
4 the preceding paragraph require accurate information as they are considered labeling.  
5 Deposition of Christine Brauer, May 23, 2014, attached as Exhibit 68, 216:1-217:20.

6 71. On August 29, 2005, the FDA cleared the G2 device for market with a  
7 permanent indication only. Letter from FDA to Bard Peripheral Vascular, August 29,  
8 2005, attached as Exhibit 69, FDA\_PRODUCTION\_00000055-56.

9 72. The IFUs for the Recovery and G2 Filter Family failed to warn of the  
10 increased risk of adverse events, such as migration or movement of the filter, with those  
11 filters versus the SNF and competitor filters—despite Bard knowing this was important  
12 information for a physician to be aware of. Ex. 63, at BPV-17-01-00137389-92; Ex. 34,  
13 Wong Dep. at 88:2-89:3; Ex. 84, Sullivan Dep. at 464:25-466:22.

14 73. Bard’s former Western Regional Sales Manager, Jack Sullivan, testified that  
15 in marketing the G2 filter Bard represented to physicians, patients and the public that: the  
16 Recovery was properly and thoroughly tested, Ex. 51, Sullivan Dep. at 62:7-18; the  
17 Recovery filter was just as migration resistant as the SNF, *id.* at 96:10-97:4; migration  
18 was not occurring more frequently with the Recovery versus competitor filters, *id.* at  
19 68:16-70:20; the Recovery filter was better than the SNF and its competitors, *id.* at 80:16-  
20 81:12; the Recovery was more likely to stay centered and avoid tilt than other filters, *id.* at  
21 81:13-83:21; and the G2 was even more resistant to fracture and migration than the  
22 Recovery, *id.* at 92:21-93:8.

23 74. The IFUs for the G2 (and Recovery) filters include identical language  
24 implying that the risk of various adverse events associated with the G2 Filter Family are  
25 the same as all other IVC filters. Ex. 63, at BPV-17-01-00137389-92 (under “Potential  
26 Complications” stating “Movement or migration of the filter is a known complication of  
27 vena cava filters.”); Recovery Filter IFU, 2004, attached as Exhibit 70, BPV-COMP-  
28 00001317-19, at 17 (same). For example, those IFUs state that migration and movement



1 are “known complications of vena cava filters.” *Id.* This is the same language Bard  
2 conveyed to physicians in its “Dear Doctor” and “Dear Colleague” letters. 2004 Recovery  
3 Filter System Dear Doctor Letter, attached as Exhibit 71, BPVE-01-00303515-16, at 16.  
4 There is nothing about that language that advises physicians or patients of the increased  
5 risk of those adverse events with the Recovery/G2 Filter Family versus the SNF or  
6 competitor IVC filters—it is just a general statement about IVC filters. Ex. 34, Wong  
7 Dep. at 88:2-89:3; Ex. 51 and 84, Sullivan Dep. at 54:10-55:6, 56:2-57:2, 59:15-61:4;  
8 460:3-466:22.

9 75. Dr. Brauer testified that as to increased migration resistance and enhanced  
10 fracture resistance the statements in Bard’s labeling and marketing materials for the G2  
11 were not accurate when comparing the G2 to the SNF. Ex. 68, 2014 Brauer Dep. at  
12 224:6-225:15.

13 76. Despite advertising the G2 filter as being 12 times more resistant to fracture,  
14 Bard did not conduct thorough testing to support that claim. Bard’s engineers did not  
15 conduct thorough testing because it concluded that data “would still fall outside of the  
16 acceptable range” and the engineers “didn’t think the answer would support our design  
17 change as a viable option.” Email chain between Micky Graves and Charlie Simpson,  
18 March 23, 2006, attached as Exhibit 72, BPVE-01-01225832.

19 77. By November 2005, Bard was aware of a concerning signal for perforations  
20 with the G2 that needed to be investigated. On November 10, 2005, Chris Ganser, Bard’s  
21 V.P. of Quality Assurance, Environmental Services & Safety, wrote: “It’s obvious from  
22 the table below and the attached MAUDE summary that there are some major  
23 discrepancies regarding the number of complaints, units sold, rates, etc. for G2. Your first  
24 cut at MAUDE Analysis sends some signals for caval perforation and deployment that  
25 have to be investigated expeditiously.” Email chain between Chris Ganser, Gin Schultz,  
26 Cindi Walcott, and others, November 7-14, 2005, attached as Exhibit 73, BPVE-01-  
27 01510714-16, at 14.  
28



1           78.     The reported perforation rate for the G2 filter in November 2005 was  
2 approximately ten times that of the SNF. Bard internal spreadsheet of Filter Sales and  
3 MAUDE data through November 7, 2005/Q3 2005, attached as Exhibit 74, BPVE-01-  
4 01510717 (showing “Caval Perforation” rates of .1336% for G2 and .0090% for SNF).

5           79.     Bard was also aware by late 2005 that the G2 did not have increased  
6 migration resistance over the Recovery or the SNF and in fact appeared to have increased  
7 rates of caudal migration than both the Recovery and SNF, despite Bard’s representations  
8 to the contrary. Ex. 62, BPV-17-01-00001134-153, at 146, 151 (initial product  
9 performance specifications for migration resistance for G2 not equivalent to SNF); Ex. 34,  
10 Wong Dep., at 146:13-23, 147:21-148:4 (Recovery and SNF were both more resistant to  
11 caudal migration than the G2 Filter); Meridian Vena Cava Filter and Jugular Delivery  
12 System Product Performance, attached as Exhibit 75, BPV-17-01-00148748-49, at 48  
13 (Bard notes in internal performance specifications for Meridian filter that its G2 line of  
14 filters “have been shown to have undesirable caudal migration resistance”); Ex. 7, Brauer  
15 2017 Dep. at 249:19-250:6 (Based on internal Bard documents, in the first three to six  
16 months that the G2 was on the market it showed stability problems that were not an  
17 improvement over the SNF).

18           80.     David Ciavarella, M.D., Bard’s medical and clinical affairs director, stated  
19 in a December 23, 2005, email, “The G2 is a permanent filter, we also have one (the SNF)  
20 that has virtually no complaints associated with it. Why shouldn’t doctors be using that  
21 one rather than the G2?” Email chain between David Ciavarella, Cindi Walcott, and  
22 others, December 20-27, 2015, attached as Exhibit 76, at BPVE-01-00028224.

23           81.     Bard knew from reports by mid-2006 that the G2 had a problem with caudal  
24 migration and tilt that it didn’t expect when they launched the G2, and these were caused  
25 by design problems with the G2 that needed to be fixed before it launched the EVEREST  
26 study of its IVC filters. Ex. 7, Brauer 2017 Dep. at 242:16-243:15; 257:9-258:19.

27           82.     By February 15, 2006, a Bard Health Hazard Evaluation characterized the  
28 “Severity” of the migration problems with the G2 as “Critical” and stated that “the cases

reported in the literature have not been as frequently associated with significant caudal movement (such as down to the iliac veins) or filter tilting and malpositioning as have been reported for the G2 filter” and that a “high percentage of caudal migrations accompanied by significant filter tilting and limb displacement.” Health Hazard Evaluation, Feb. 15, 2006, BPVEFILTER-01-00008355-57, at 55, 57, attached as Exhibit 77.

83. The G2 failed to perform as well as the SNF and Recovery filters on Bard’s caudal migration push test, Project 8049. The September 19, 2006, report from that testing stated that the SNF was statistically superior to the G2 and Recovery in migration resistance. Caudal Migration Test Method Development and G2 Filter Resistance Test Report, attached as Exhibit 78, BPVE-01-007895432-55.

84. On November 30, 2008, a Modified Recovery (G2) filter investigation under a heading “What is G2 Trend Relative to RNF?” contained the following data demonstrating the G2 was inferior to the Recovery as to caudal migration, tilt and perforation:

### **What is G2 trend relative to RNF?**

|                    | G2  | RNF* | Comments                     |
|--------------------|-----|------|------------------------------|
| Caudal Migration   | 14% | 3%   | G2 more caudal than RNF      |
| Cephalad Migration | 4%  | 4%   | Same                         |
| Tilt               | 39% | 16%  | G2 more tilt than RNF        |
| Perforation        | 36% | 9%   | G2 more perforation than RNF |

18

\* RNF Data is through 7/31/06 which is the majority of RNF Complaint data (n=114/150) due to last major analysis

G2 and G2 X Fracture Analysis, November 30, 2008, attached as Exhibit 79, BPVE-01-01239757-775, at 774.

1           85.     Caudal migration is a serious complication with an IVC filter that can be  
2 associated with serious adverse events and consequences. Ex. 7, Brauer 2017 Dep. at  
3 240:4-22.

4           86.     By April 2006, Bard was aware that caudal anchors had been added to the  
5 Greenfield IVC filter to deal with caudal migration. Memo from Natalie Wong re G2 Pre-  
6 Product Assessment Team Minutes-Caudal Migration, April 28, 2006, attached as Exhibit  
7 80, BPVE-01-00717924-25, at 24 (discussing that Greenfield filter was redesigned by  
8 flipping two hooks to prevent caudal migration after problems with caudal migration  
9 emerged during the Greenfield clinical trial).

10          87.     By March 2, 2006, Bard determined that the G2 filter propensity for caudal  
11 migration represented an “unacceptable risk” of serious injury and death. G2 Caudal  
12 Migration report, March 2, 2006, attached as Exhibit 81, BPVE-01-00720835.  
13 Nonetheless, Bard took no “preventative action” to warn physicians or patients about the  
14 “unacceptable risk.” Wong Dep. at 155:10-25; 156:10-12; 179:4-7; 181:18-22.

15          88.     Bard did not share with the FDA pertinent safety testing data concerning  
16 migration resistance for its IVC filters and upon discovery that this information was not  
17 shared with the FDA, Bard contacted its legal counsel instead of the FDA. Memo from  
18 Brian Barry to John Weiland re Competitive Filter Data, May 2, 2005, attached as Exhibit  
19 82, BPV-01-00098737.

20          89.     Bard’s own internal complaint tracking data indicates that from market  
21 release through July 2010, the G2 Filter had a reported migration failure rate of 0.121%  
22 (1.21 out of every 1000) of all devices sold and a reported perforation failure rate of  
23 0.132% (1.3 out of every 1000), which applying the “consensus” of 95-99% of similar  
24 events not reported, the actual rates could have been as high as 121 out of every 1000  
25 (12.1%) and 130 out of 1000 (13%), respectively. This figure was approximately fifteen  
26 times greater than the average for all competitor devices of .008% (or .8% if applying the  
27 consensus non-reported events rate) for migrations and .013% (1.3%) for perforations.  
28 Bard IVC filter model sales and complications comparison spreadsheet, attached as

1 Exhibit 83, BPVEFILTER-01-00050487-88; Ex. 113, Ciavarella Dep, at 130:14-131:23  
2 (“general consensus” that only 1-5% of adverse events are voluntarily reported).

3 90. Bard’s EVEREST clinical trial revealed that 15 of 85 Patients (18%)  
4 experienced filter tilt > 15 degrees, and that there was highly statistically significant  
5 relationship between filter tilt and filter migration ( $p < 0.001$ ). Binkert, et al., Technical  
6 Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study, J.  
7 Vasc. Interv. Radiol. 2009, attached as Exhibit 85, at 1452.

8 91. Dr. Kris Kandarpa, the Medical Monitor of the EVEREST trial, expressed  
9 his concern about the approximately 20% of reported tilts and “thought that Bard should  
10 consider a redesign based on this information.” He wanted to know if those conducting  
11 the study were concerned that “almost 50% of patients have a reported AE/SAE” (adverse  
12 or serious adverse event). Medical Monitoring Adjudication Meeting Minutes, August 28,  
13 2006, attached as Exhibit 86, BBA-00012802-821, at 803. Dr. Brauer agreed Bard should  
14 have taken “certain follow-up actions” in response to Dr. Kandarpa’s concerns. Ex. 7,  
15 Brauer 2017 Dep. at 274:18-275:4.

16 92. The October 26, 2006 Medical Monitoring Adjudication Meeting Minutes  
17 states, “Dr. Kandarpa noted that approximately 30% of the patients in this trial had a  
18 device observation,” and also “expressed concern over the number of device observations  
19 but noted that it was not in his charter to determine study stopping.” Dr. Kandarpa also  
20 noted that “half the technical observations are tilts.” Medical Monitoring Adjudication  
21 Meeting Minutes, October 26, 2006, attached as Exhibit 87, BBA-00013699-715, at 700.

22 93. A May 28, 2008, Bard PowerPoint presentation reviewing its IVC filter  
23 product line included a Strengths-Weaknesses-Opportunities-Threats (SWOT) analysis  
24 which identified among Bard’s “Weaknesses” as to IVC filters: (1) “Lack of thorough  
25 understand dynamics of caval anatomy impacting test results,” (2) “We have historical  
26 reactive/evolution design mindset,” (3) “Product complications – forcing focus on reactive  
27 designing??” Bard Peripheral Vascular Filter Franchise Review, May 6, 2008, attached as  
28 Exhibit 88, BPVE-01-00622862-900, at 67. Dr. Ciavarella agreed that Bard did not “have

any good models or understanding of what happens to the cava.” Ex. 84, Ciavarella Dep. at 374:1-14; *see also* Ex. 21, DeCant Dep. at 70:22-71:17 (Bard continued to learn about the vena cava after its IVC filters were on the market).

94. By June 2008, Bard had identified the need to make material improvements to the G2 filter to reduce migration, tilt, fracture, and perforation. Bard PowerPoint Presentation, attached as Exhibit 89, Ex. 534 to Chris Ganser Deposition (Oct. 11, 2016), at 3-13; G2 Platinum presentation, June 2008, attached as Exhibit 90, BPVE-01-00624026, at 33. At the time, Bard tied caudal migrations to causing tilt, perforation, and fractures. Ex. 85 at 8, 12; Ex. 86, at 41.

**D. The G2X Filter.**

95. On March 10, 2008, Bard submitted a special 510(k) application (K080668) seeking to modify its G2 filter (which was the predicate device) and seeking clearance for what would be known as the G2 Express. G2 EXPRESS™ Filter System – Femoral and Jugular/Subclavian Delivery Kits 510(k) Summary, *available at* <https://www.fda.gov/cdrh/510k/K080668.pdf> (last accessed Oct. 2, 2017).

96. The only modification to the G2X from the G2 was the addition of a snare hook to improve retrievability of the filter; the G2 and G2X filters are the same filter. Deposition of Patrick McDonald, July 29, 2016, attached as Exhibit 91, at 103:23-104:1; Ex. 34, Wong Dep. at 182:18 – 182:7; Email chain between Brian Hudson, Kevin Bovee, and Chad Modra, June 28, 2011, attached as Exhibit 92, BPVEFILTER-01-00037661-62.

97. By November 30, 2008, Bard had further test results and information that the G2 and G2X filter had significantly higher rates of caudal migration, tilt, and perforation than even the Recovery. Ex. 79, BPVE-01-01239757, at 74.

98. A 2009 study demonstrated that after 180 days, the Bard IVC filters began to fracture. F.C. Lynch & S. Kekulawela, *Removal of the G2 Filter: Differences between Implantation Times Greater than and Less than 180 Days*, 20 J. Vasc. Interv. Radiol. 1200 (2009), attached as Exhibit 93. Subsequently, in 2010, another study demonstrated that Bard’s filters had an increasing fracture rate over time and an expected fracture rate

1 of approximately 25 percent at 50 months. W. Nicholson et al., *Prevalence of Fracture*  
 2 *and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical*  
 3 *Implications Including Cardiac Perforation and Tamponade*, 170 Arch. Intern. Med. 1827  
 4 (2010), attached as Exhibit 94.

5 99. Bard knew that fracture, tilt, and perforation were caused by migration,  
 6 including caudal migration. Ex. 85, at 8, 12; Bard Idea POA Eclipse Anchor Filter,  
 7 attached as Exhibit 95, BPVE-01-02077858, at 58 (“This improvement in caudal  
 8 migration resistance should reduce subsequent tilt, fracture, and penetration.”). Bard  
 9 knew the G2 and G2X filters had increased rates of caudal migration as compared to the  
 10 Recovery. Ex. 95, at BPVE-01-02077858. Bard was aware that the physician perception  
 11 was that “design sacrifices” were made for its optional filters that led to higher rate of  
 12 movement or migration, which Bard knew led to an increased risk of fracture. *Id.*

13 **E. The Eclipse Filter.**

14 100. Bard’s next generation filter, the Eclipse, was cleared for sale in the United  
 15 States on January 14, 2010. Deposition of Daniel Orms, Aug. 16, 2016, attached as  
 16 Exhibit 96, at 134:4-134:17.

17 101. The Eclipse was predicated on the G2 and G2X, and was represented as an  
 18 improvement over the G2X filter. *Id.* at 135:19-22; *see also* Ex. 84, Sullivan Dep. at  
 19 531:4-8, 533:18-22; Deposition of Christopher Smith, Aug. 3, 2017, attached as Exhibit  
 20 97, at 144:16-20; Deposition of Michael Randall, Feb. 2, 2017, attached as Exhibit 98, at  
 21 267:11-14.

22 102. The Eclipse name change was merely to “break with the baggage associated  
 23 with the previous versions [Recovery and G2].” Email from Filter Marketing to Bill  
 24 Little, Apr. 27, 2010, attached as Exhibit 99, at BPVE-01-00580608. But, the Eclipse  
 25 “was the same as G2X in every way but one.” *Id.* That one difference – electropolishing  
 26 – was to be “consistent with emerging industry standards.” Vail Vena Cava Filter  
 27 Concept POA, Oct. 14, 2009, attached as Exhibit 101, BPV-17-01-00145692-99, at 95.  
 28

1           103. The Eclipse was marketed at a time when Bard understood that its venture  
2 into the retrievable filter space has been a public health disaster and that Bard needed to  
3 completely redesign its filter. Ex. 85, at 13-16.

4           104. By August 2010, Bard had identified 172 fractures in G2, G2X, and Eclipse  
5 filters. Filter Fracture Analysis, August 2010, BPV-17-01-00170378-85, at 79, attached  
6 as Exhibit 100. Of those, 60% were discovered at retrieval – meaning most fractures  
7 continued not to be discovered without doctor invention. *Id.* It also knew that both the  
8 number of fractures and rate of fractures had increased since the full market release of the  
9 G2. *Id.* at 81.

10           105. Instead of pulling out of the retrievable filter market while it fixed its filters’  
11 known design flaws, Bard created the Eclipse (originally named “Vail”) as a re-branding.  
12 Ex. 100, BPV-17-01-00145692-99, at 98 (“We will take advantage of the opportunity to  
13 rebrand the filter with this launch. We will promote it with a new name, new packaging,  
14 and new product codes.”).

15           106. During this same time period, Bard was also actively engaged in  
16 development of its Denali filter. Deposition of Brett Baird, June 9, 2016, attached as  
17 Exhibit 102, at 262:12-20.

18           107. Nevertheless, Bard promoted the Eclipse to its sales personnel as more  
19 resistant to fracture and as having enhancements to a number of complications seen in  
20 prior iterations, which doctors were interested in. Ex. 97, Smith Dep. at 141:18-24, 126:6-  
21 18, 130:6-20, 156:5-156:25, 184:9-21.

22           108. However, Abithal Raji-Kubba, Bard’s Vice President of Research and  
23 Development, confirmed that there was no evidence that the Eclipse improved resistance  
24 to fracture, migration or corrosion. Deposition of Abithal Raji-Kubba, dated July 18,  
25 2016, attached as Exhibit 103, at 167:18-168:2.

26           109. The Eclipse Product Performance Specification 3.1.7 addressed the “User  
27 Need” that the “filter does not migrate” but included no performance standard  
28 or testing relating to caudal migration resistance. Design History File Index,



1 Exhibit 104, BPV-17-01-00108342 at 473; First Supplemental Expert Report of  
2 David A. Kessler, M.D. (Mar. 3, 2017), attached as Exhibit 105, at 2.

3 110. In addition, Bard continued to apply the migration resistance standard of  
4 50 mmHg in a simulated IVC diameter of 28 mm, which was inadequate and not  
5 comparable to the SNF. Ex. 106, Design History File Index for the Eclipse, BPV-17-01-  
6 00108342, at 473; Exhibit 105, Kessler First Supp Report at 2.

7 111. Bard represented the Eclipse Filter as designed to be a permanent implant.  
8 Ex. 97, Smith Dep. at 155:6-156:4; Eclipse Patient Questions & Answers Brochure,  
9 attached as Exhibit 107, BPVEFILTER-01-00001631-32, at 32.

10 112. An Eclipse patient brochure stated, “The Eclipse Filter does not have a time  
11 limit in which it must be removed. Your physician can determine at which time it may be  
12 appropriate to have your Filter removed.” Ex. 97, Smith Dep. at 158:1-159:5.

13 **F. Problems and Failures with all of Bard’s Retrievable IVC Filters.**

14 113. As part of its response to a deficiency letter Bard received from the FDA on  
15 May 13, 2015, Bard stated that “the first SNF 510(k) was cleared on April 20th 1990  
16 (K894703) and has been on the US market for 24 years as a permanent Inferior Vena  
17 Cava (IVC) filter option. Throughout its over two decades of clinical use, no evidence  
18 has been found to support a link between SNF permanent filter implantation and the  
19 serious health consequences that have been an expressed concern from FDA regarding  
20 removable IVC filters . . .” SNF Postmarket Surveillance Study Amendment: 522  
21 Response, 2015, BPVEFILTER-01-00356101, attached as Exhibit 108, at 106.

22 114. Bard’s June 2011 internal analysis demonstrated that the Recovery filter  
23 fractured 55 times more often than the SNF; the G2 fractured more than 12 times as often  
24 as the SNF, the G2X fractured 10 times as often as the SNF, and the Eclipse, even after  
25 only a little over a year on the market, fractured over three and a half times as often as the  
26 SNF. Ex. 5, BPVEFILTER-01-00037664.



1           115. Chris Ganser was Vice President of Regulatory Sciences and Corporate  
2 Head (Vice President) of Quality Assurance, Regulatory Affairs and Medical Affairs  
3 testified as summarized below:

- 4           a. Bard knew and should have communicated to physician and patients  
5 statistically significant findings that Bard's Recovery filters revealed  
6 increased risks and complications compared to the predicate device.  
7 Deposition of Christopher Ganser, Oct. 11, 2016, attached as Exhibit  
8 109, at 68:9-69:10; 263:17-264:7.
- 9           b. Bard knew and should have communicated to physician and patients  
10 that tilting was a condition that could put a patient at an increased  
11 risk of perforations, migrations, fracture, and could adversely affect  
12 the device's ability to work for its intended purpose of stopping  
13 pulmonary embolisms. *Id.* at 71:5-72:9; 82:2-5.
- 14           c. Bard knew and should have communicated to physician and patients  
15 that tilting could lead to further movement of its filters that results in  
16 embedment making it irretrievable via a percutaneous approach. *Id.*  
17 at 72:22-75:4; 76:6-21; 78:11-79:3.
- 18           d. Bard knew but did not communicate to patients that an inability to  
19 retrieve a filter percutaneously may necessitate an open procedure.  
20 *Id.* at 78:11-18.
- 21           e. Bard knew, but did not, communicate to physician and patients to  
22 evaluate devices over time to make sure they stay centered. *Id.* at  
23 71:5-72:9.
- 24           f. Bard knew physicians and patients did not have access to Bard's  
25 Bench testing of Bard filters and also knew that physicians and  
26 patients were unable to do their own risk benefit analysis. *Id.* at  
27 128:2-15.  
28

- 1           g.     Bard knew, but did not, communicate to physicians and patients its  
2                 internal analysis concluding G2 products were experiencing  
3                 undesirable risk of caudal migration. *Id.* at 292:18-294:9.
- 4           h.     Bard knew, but did not, communicate to physicians and patients and  
5                 the IFU did not say that the Recovery filter design did not have the  
6                 ability to carry out its intended function of preventing pulmonary  
7                 embolisms. *Id.* 268:4-269:6.
- 8           i.     Bard knew, but did not, communicate to physicians and patients  
9                 statistically significant findings of fatalities, the fact that Bard was  
10                redesigning and had determined that Recovery was not performing as  
11                Bard expected and intended it to perform. *Id.* at 260:14-261:4.
- 12          j.     Bard knew, but did not, communicate to physicians and patients that  
13                 the G2 filter had an undesirable risk profile based on Dr. Ciavarella's  
14                 February 2006 Health Hazard Evaluation and needed to be  
15                 redesigned to address issues. *Id.* at 292:18-294:9.
- 16          k.     Bard knew that the G2 needed to be redesigned to deal with  
17                 migration, tilt, and penetration to deal with risks and complications  
18                 identified in the February, 2006 HHE. *Id.* at 300:5-301:21.

19           116.   Clement Grassi, MD is a Bard expert who has been involved in developing  
20                 practice parameter guidelines for the Society of Interventional Radiology (SIR) and the  
21                 American College of Radiology (ACR). Dr. Grassi testified:

- 22           a.     SIR and ACR consensus statement regarding informed consent for  
23                 procedures that include IVCs, and he agrees with the concept that  
24                 informed consent would require taking into consideration what "a  
25                 reasonable patient would want to know in the same or similar  
26                 circumstances. Deposition of Clement Grassi, M.D, dated July 30,  
27                 2014, attached as Exhibit 110, at 232:14-19.
- 28

- 1           b.     The risks and expected benefits of the procedure and the alternatives  
2                 have to meet not only the perceptions of a physician, but what a  
3                 reasonable patient would want to know in the same or similar  
4                 circumstances. *Id.* at 238:2-239:2.
- 5           c.     Dr. Grassi agreed that manufacturers should not make decisions  
6                 about what reasonable patients should know or not know or what  
7                 reasonable physicians should know or not know regarding risk/benefit  
8                 decisions. *Id.* at 239:3-17.
- 9           d.     Findings that Bard filters experienced complications, including death,  
10                migration, perforation, and fracture that were higher than other filters  
11                on the market is information that a reasonable patient might want to  
12                know. *Id.* at 325:15-326:6.

13           117.   Natalie Wong, Bard Quality Engineering Manager, testified that the  
14           Recovery filter had statistically significant higher rates of filter migration, IVC  
15           perforation, and filter fracture compared to competitor filters and its own filter. It should  
16           have been important for physicians to have this information. Ex. 34, Wong Dep. at 17:9-  
17           15, 84:21-87:25.

18           118.   Ms. Wong also testified that Bard did not have an internal system regarding  
19           the number of filter fractures during a single month. *Id.* at 17:9-15, 138:15-22.

20           119.   According to Ms. Wong, physicians and patients were not informed of  
21           Bard's internal risk analysis that concluded G2 posed an unacceptable risk of caudal  
22           migration. *Id.* at 151:19-155:14; 180:17-181:22.

23           120.   Ms. Wong confirmed that the G2 and G2X are the same filter design with  
24           the exception of a snare hook removal that was added to the G2X. There were no changes  
25           to the filter portion itself. *Id.* at 182:18-183:7.

26           121.   John McDermott, President of Bard Peripheral Vascular from 1999 to 2008,  
27           testified that doctors would want to know information and data, including adverse events  
28           of Bard's devices compared to other devices from the perspective of safety and efficacy.

1 He also testified that doctors would want to know the information Bard had about other  
2 doctor's experiences with filters. Mr. McDermott agreed that this data and information  
3 are important to doctor's decision making. Ex. 2, McDermott Dep. at 142:18-144:1;  
4 152:16-154:4; 166:9-168:18; 288:13-289:7; 290:15-291:18.

5 122. Mr. McDermott testified that a multi-disciplinary panel of physicians in  
6 June 2004 advised him and other managerial members of Bard that "migration should not  
7 be different for retrievable filters than for permanent filters;" that a retrievable filter is  
8 expected to perform just as well as a permanent filter; and for "prophylactic filter  
9 placement, migration of the heart should virtually never happen." *Id.* at 190:11-195:13;  
10 196:12-197:16; G3 Vena Cava Filter Design Input Summary Report, BPVE-01-0061776,  
11 attached as Exhibit 111.

12 123. Mr. McDermott agreed that medical device companies have an obligation to  
13 provide all relevant information necessary to doctors to make product choices. He also  
14 agreed that the company has an obligation to educate and inform doctors with information  
15 about complications and trending of adverse events. Ex. 2, McDermott Dep. at 228:17-  
16 229:8; 349:17-21.

17 124. Bard possessed information that the Recovery and G2 filters had a  
18 considerably higher rate of fractures than the SNF. *Id.* at 284:2-286:18; Ex. 92 at  
19 BPVEFILTER-01-00037661.

20 125. Mr. McDermott monitored the increasing rates of complications of  
21 Recovery and G2 on a monthly basis and he acknowledged what he was seeing was  
22 underreported and that the numbers of adverse events—including deaths, migrations and  
23 fractures—kept going "up and up and up" month after month. Ex. 2, McDermott Dep. at  
24 306:14-308:10.

25 126. Bard's regulatory and industry standard expert, Dr. Brauer agreed if a device  
26 as cleared and designed does not meet its performance requirements or acceptance  
27 criterion for caudal migration the company should stop selling it. Ex. 7, 2017 Brauer Dep.  
28 at 386:10-19.

127. Dr. Brauer also agreed “[i]t is important for medical device manufacture to understand healthcare professionals’ expectations for performance of a product.” Ex. 7, 2017 Brauer Dep. at 334:4-14.

128. Bard’s retrospective analysis of fractures in its G2, G2X, and Eclipse filter groups shows that both the number of fractures and the cumulative fracture rate increased consistently over time. Filter Fracture Analysis, May 2016, attached as Exhibit 112, BPVEFILTER-01-00303182-89, at 82-86.

**G. The SIR Quality Improvement Guidelines do not Establish a Safety Standard.**

129. The SIR Quality Improvement Guidelines predate all of Bard’s optional filters, including among others the Recovery, G2 and G2X. Ex. 110, Grassi Dep. at 69:23-70:10; Deposition of David Ciavarella, dated November 12, 2013, attached as Exhibit 113, at 220:16-221:15.

130. Bard’s former medical director from 2004-2008, David Ciavarella testified that the SIR Quality Improvement Guidelines did not create safety thresholds for the filters. Ex. 113, Ciavarella Dep. at 220:16-221:15.

**H. Bard Kept its Sales Staff in the Dark About the Problems with its Retrievable IVC Filters.**

131. Robert Cortelezzi was a Bard regional sales manager from 2004 to 2008. Deposition of Robert Cortelezzi, Nov. 11, 2016, attached as Exhibit 114, at 15:21-16:24.

132. As a regional sales manager, Mr. Cortelezzi was not privy to each and every event reported to or collected by Bard that concerned filter perforation, migration, tilt or fracture. *Id.* at 276:2-272:2.

133. Mr. Cortelezzi expected and relied that Bard would thoroughly, accurately and completely test each and every product for any known or potential complication before it was launched and went into the market launched. *Id.* at 289:15-290:4.

134. Bard represented the G2 Filter as a filter that would remain centered and less likely to tilt and migrate and was improved compared to other filters, including the Recovery Filter. *Id.* at 306:1-307:7.

1           135. Mr. Cortelezzi expected that Bard would thoroughly evaluate the safety of  
2 its products before launching them into the market and failure to do so would be contrary  
3 to his reasonable expectations as a regional manager. *Id.* at 308:13-23.

4           136. Mr. Cortelezzi never received a Health Hazard Evaluation or document that  
5 compiled all complications or adverse events. *Id.* at 320:22-324:5.

6           137. The Bard sales force was not armed with a Health Hazard Evaluation to  
7 provide doctors information when promoting Bard products. *Id.* at 323:15-324:5.

8           138. Mr. Cortelezzi was not aware of specific events in which “[s]erious injury or  
9 potential serious injury was seen in nine cases where fragments migrated to the heart or  
10 lung.” *Id.* at 324:6-327:7; *see also* Health Hazard Evaluation, dated Nov. 17, 2004, BPV-  
11 17-01-00103875, attached as Exhibit 115.

12           139. Referring to an e-mail from Janet Hudnall to Shari Allen, dated January 19,  
13 2005, reporting deaths in bariatric patients associated with Recovery Filter migration,  
14 Mr. Cortelezzi did not receive the information and did not arm his sales force with the  
15 information. Ex. 114, Cortelezzi Dep. 327:9-331:22.

16           140. Daniel Orms was a Bard regional sales manager from 2008 to 2012. Ex. 96,  
17 Orms Dep. at 14:8-23.

18           141. Mr. Orms testified that information in Bard’s possession about Recovery  
19 Filter events which caused injury or potential injury would have been helpful in  
20 discussions with doctors. *Id.* at 173:14-174:24.

21           142. Mr. Orms testified it would have been reasonable for him and his sales  
22 people to be advised by Bard about tracking of events. However, the practice of  
23 communicating Bard tracking events to sales did not occur. Ex. 96, Orms Dep. at 175:1-  
24 10.

25           143. Regional sales manager Jack Sullivan testified that he expected Bard to  
26 share all information that was relevant to Filter safety with the sales force. Ex. 84,  
27 Sullivan Dep. at 468:18-469:3.  
28

1 144. Mr. Sullivan expected Bard to communicate any information relevant to  
 2 safety or the lack thereof so that he and his sales force could communicate the information  
 3 to physicians. *Id.* at 469:4-15.

4 145. Tim Fischer was employed by Bard between 2000 to 2006. He was a  
 5 territory manager then field sales manager. Deposition of Tim Fischer, Mar. 29, 2017,  
 6 attached as Exhibit 116, at 7:16-24.

7 146. As a former sales representative, Timothy Fischer was never provided by  
 8 Bard information regarding numbers of events concerning the Recovery Filter. *Id.* at  
 9 281:13-283:1.

10 147. Mr. Fischer testified that once Bard tracked event information, if Bard  
 11 thought it was important, he would have wanted to have it to present to physicians. *Id.* at  
 12 282:4-283:3.

13 148. Bard did not provide tracked Filter events to Mr. Fischer. *Id.* at 283:3.

14 149. Defense medical expert Mark Moritz testified in reviewing reports of  
 15 plaintiffs' experts he saw references to Bard internal documents which spoke to serious  
 16 injuries and even death caused by failure modes of Bard filters. This is information a  
 17 medical doctor would want to know from a medical device company when making  
 18 decisions about which types of devices to use for patients. Deposition of Mark Moritz,  
 19 M.D., dated July 18, 2017, attached as Exhibit 117, at 85:12-86:3.

## 20 **II. FACTS RELATED TO HYDE V. BARD**

21 150. A Bard G2X IVC filter was implanted in Plaintiff, Lisa Ann Hyde on  
 22 February 25, 2011 [REDACTED]  
 23 [REDACTED] [Ex. H-A, Selected Plaintiff Medical Records at  
 24 HYDE\_[REDACTED]\_MDR00172; Ex. H-B, April 6, 2017 Deposition, [REDACTED]  
 25 Deposition Transcript at 65:9-11.]

26 151. Plaintiffs were [REDACTED] residents at the time Ms. Hyde had her filter  
 27 implanted. [Ex. H-D PFS at § I.5.]  
 28

1 152. [REDACTED] IVC filter implantation. [Ex.  
2 H-A, Selected Plaintiff Medical Records at HYDEL\_[REDACTED]\_MDR00172.]

3 153. [REDACTED], M.D. was the [REDACTED] and testified that he believes  
4 Ms. Hyde's filter was a G2X IVC filter. [Ex. H-B, [REDACTED] Deposition at 11:22-24.]

5 154. [REDACTED]  
6 [REDACTED]. [Ex. H-A,  
7 HYDEL\_[REDACTED]\_RAD00009-10.]

8 155. [REDACTED]  
9 [REDACTED]  
10 [REDACTED]. [Ex. H-A, HYDEL\_[REDACTED]\_RAD00009-10;  
11 HYDEL\_SHC\_MDR00019 to 20.]

12 156. [REDACTED]  
13 [REDACTED] [Ex. H-C, Lisa Hyde Deposition Transcript at 18:9-22; Ex. H-D, PFS at I.5.]

14 157. [REDACTED]  
15 [REDACTED]  
16 [REDACTED]. [Ex. H-A,  
17 HYDEL\_[REDACTED]\_RAD00008.]

18 158. [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED] [Ex. H-A, HYDEL\_[REDACTED]\_MDR00075-76.]

22 159. [REDACTED]  
23 [REDACTED]. [Ex. H-A, HYDEL\_[REDACTED]\_MDR0002-04.]

24 160. [REDACTED]  
25 [REDACTED]  
26 [REDACTED]. [Ex. H-  
27 A, HYDEL\_[REDACTED]\_MDR0002-04.]  
28



- 1 161. [REDACTED] G2X filter [REDACTED]  
 2 [REDACTED]. [Ex. H-D PFS at § II.10(a)-(c).]
- 3 162. [REDACTED] Bard G2X in his  
 4 records. [Ex. H-E, Deposition of [REDACTED] at 23:12-15, 48:21-24.]
- 5 163. [REDACTED] a Bard  
 6 G2X filter. [Ex. H-A, HYDEL\_[REDACTED]\_MDR00055.]
- 7 164. [REDACTED]  
 8 [REDACTED]  
 9 [REDACTED]. [Ex. H-B, [REDACTED] Dep. Tr. at 46:1-25.]
- 10 165. [REDACTED]  
 11 [REDACTED]  
 12 [REDACTED] [Ex. H-B, [REDACTED] Dep. Tr. at 56:17-18.]
- 13 166. There is no design difference between the G2 and G2X filters. [Ex. H-F,  
 14 McMeeking Dep. Tr. at 37:9-39:8.]
- 15 167. Bard failed to design the G2 and G2X filters in a way that reduces the risks  
 16 of tilting, perforation, migration and fracture by fatigue. [Ex. H-F, McMeeking Dep. Tr. at  
 17 23:14-23.]
- 18 168. Bard could have redesigned the filter configuration to find a better  
 19 combination of phenomena that improved the behavior of the filter in terms of the risks  
 20 involved. They could have developed caudal anchors and penetration limiters sooner than  
 21 they ultimately did. [Ex. H-F, McMeeking Dep. Tr. at 32:14-33:8.]
- 22 169. Anchors and limiters are a reasonable concept for how the tilt and migration  
 23 behavior of a filter can be limited. [Ex. H-F, McMeeking Dep. Tr. at 129:24-130:1.]
- 24 170. Bard should have considered other a different design of the G2/G2X that  
 25 included using a tubing material, arms with different diameters and dimensions, or a  
 26 different number of arms. [Ex. H-F, McMeeking Dep. Tr. at 30:23-31:5; 34:13-23.]  
 27  
 28

1 171. Bard did inadequate testing in assessing the performance of the design and  
2 consequences of the design of the G2 and G2X filters. [Ex. H-F, McMeeking Dep. Tr. at  
3 308:1-9.]

4 172. It is the design of the G2 and G2X filters itself that causes the dangerous  
5 failures. [Ex. H-F, McMeeking Dep. Tr. at 23:12-15.]

6 173. Bard's Director of Quality Assurance, Chris Ganser, said that there were  
7 design issues with the G2 filter that needed to be addressed. [Ex. H-G, October 11, 2016  
8 Deposition of Chris Ganser at 301:16-21.]

9 174. The G2 and G2X subsequently tilted after placement. [Ex. H-H, April 17,  
10 2013 Deposition of Robert Carr at 94:11-19.]

11 175. Bard tried to ultimately decide to include an anchor system so that the  
12 known causes for tilt would be reduced. [Ex. H-H, Carr Dep. Tr. at 95:22-96:6.]

13 176. SNF is more migration resistant due to the combination of the stiffness of its  
14 pedals and the stiffness of its legs as compared to the other Bard filters. [Ex. H-F,  
15 McMeeking Dep. Tr. at: 203:9-22.]

16 177. The SNF is a safer and better filter than the other Bard filters. [Ex. H-F,  
17 McMeeking Dep. Tr. at 321:11-15; 221:20-24.]

18 178. The G2 device was intended for permanent placement. [Ex. H-I, Patient  
19 Brochure for the G2 Filter System, BPV-17-01-00142912.]

20 179. All of the G2 era filters are truly permanent filters. [Ex. H-H, Carr Dep. Tr.  
21 at 32:18-23.]

22 180. [REDACTED] testified that he understood [REDACTED].  
23 [Ex. H-B, [REDACTED] Dep. Tr. at 72:23-73:1.]

24 181. [REDACTED] testified that he trusts the FDA more than medical device  
25 companies and that he is comfortable using any filter that is FDA approved. [Ex. H-B,  
26 [REDACTED] Dep. Tr. At 45:23-24 and 25:13-25.]

1           182. [REDACTED] also testified that in 2011, it was his understanding that all FDA-  
2 cleared IVC filters had the same performance and comparable risks of complications, such  
3 as migrations and fractures. [Ex. H-B, [REDACTED] Dep. Tr. At 27:25-28:10.]

4           183. [REDACTED] testified that he has read the Bard G2X instructions for use  
5 document. [Ex. H-B, [REDACTED] Dep. Tr. At 86:3-7.]

6           184. [REDACTED]  
7 [Ex. H-D, PFS at § II.15.]

8           185. Bard's own expert, Dr. Donna Tillman, states that when you design a device  
9 and you have a risk, the best thing to do to mitigate that risk is to design around it. You  
10 have to design the device so that the risk goes away. If you can't do that, Tillman says that  
11 you must implement some kind of way to protect the user against the risk. And finally, if  
12 you can't accomplish that either, you must "label around it" and tell patients there is a risk  
13 here. Tillman feels that these are "standard design considerations." [Ex. H-J, Tillman Dep.  
14 Tr. at 193:6-194:20].

15           186. Kay Fuller, a Bard Regulatory Affairs Specialist handling the Recovery  
16 510(k) application, testified that a Truthfulness and Accuracy Statement must be signed  
17 when she would submit a 510(k) application to the FDA. This document says that to the  
18 best of the signatory's knowledge, the information in the 510(k) is truthful, accurate, and  
19 does not contain any material information omitted. [Ex. H-K, Kay Fuller Dep. Tr. 46:8-  
20 22].

21           187. Ms. Fuller did not sign the Truthfulness and Accuracy statement because  
22 she was concerned that Bard would not be able to address the FDA's questions and she  
23 did not believe that the company understood the failure modes, specifically fatigue  
24 resistance, to the level that they were representing to the FDA. [Ex. H-K, Kay Fuller Dep.  
25 Tr. 125:6-25].

26           188. Additionally, Ms. Fuller did not sign because she did not feel like Bard had  
27 adequately addressed the fracture failure mode and had not put in adequate corrective  
28 actions. [Ex. H-K, Kay Fuller Dep. Tr. 129:22-130:11].

189. This was the first time in Ms. Fuller's career that she was not comfortable singing the Truthfulness and Accuracy statement in an application to the FDA. [Ex. H-K, Kay Fuller Dep. Tr. 131:24-132:8].

190. Since Ms. Fuller would not sign the Truthfulness and Accuracy statement, Carol Vierling, without permission, signed Ms. Fuller's name for her. [Ex. H-K, Kay Fuller Dep. Tr. 276:7-277:11].

### III. FACTS RELATED TO MULKEY V. BARD

191. [REDACTED] Ms. Mulkey [REDACTED] IVC filter. (Ex. M-D, Mulkey Dep. Tr. at 77:20-23; Ex. M-C, [REDACTED] Dep. Tr. at 71:12-18).

192. [REDACTED] an IVC filter [REDACTED] placement in Ms. Mulkey [REDACTED]. (Ex. M-B, Hurst Report at p. 4 ¶3(a)).

193. Ms. Mulkey was implanted with a Bard Eclipse IVC filter [REDACTED]. (Ex. M-B, Hurst Report at p. 4 ¶3(a)).

194. [REDACTED] (Ex. M-D, Mulkey Dep. Tr. at 88:5-16).

195. [REDACTED] Eclipse filter in Ms. Mulkey. (Ex. M-C, [REDACTED] Dep. Tr. at 88:23-25).

196. The Bard Eclipse filter was implanted [REDACTED] Ms. Mulkey by [REDACTED]. (Ex. M-B, Hurst Report at p. 5, ¶3(b)).

197. [REDACTED] Eclipse Filter in Ms. Mulkey, [REDACTED] had seen the IFU for the Bard Eclipse filter, and it is his practice to review the IFU for new devices prior to implanting them in patients. (Ex. M-C, [REDACTED] Depo at 105:11-23).

198. [REDACTED] is familiar with the instructions for use for vena cava filters. (Ex. M-C, [REDACTED] Dep. Tr. at 102:16-23).

199. Bard sales representatives attended the placement of filters [REDACTED] [REDACTED] provide him information if he had questions. (Ex. M-C, [REDACTED] Dep. Tr. at 210:1-13; 105:15-18).

1           200. [REDACTED] does not remember ever being told by any Bard sales  
2 representative that IVC filters [REDACTED]. (Ex. M-C,  
3 [REDACTED] Dep. Tr. at 55:14-17).

4           201. [REDACTED] told Ms. Mulkey that her Eclipse filter [REDACTED]  
5 [REDACTED] (Ex. M-D, Mulkey Dep. Tr.  
6 at 79:3-7).

7           202. [REDACTED] Ms. Mulkey's Eclipse filter [REDACTED]  
8 [REDACTED] (Ex. M-D, Mulkey Dep. Tr. at 85:20-23).

9           203. It was Dr. [REDACTED]  
10 [REDACTED]. (Ex. M-C, [REDACTED] Dep. Tr. at  
11 86:24 – 87:2).

12           204. Ms. Mulkey had the opportunity to ask [REDACTED] questions about the  
13 filter. (Ex. M-D, Mulkey Dep. Tr. at 81:19-21).

14           205. Dr. [REDACTED] testified that he did not consent [REDACTED]  
15 [REDACTED]  
16 [REDACTED] (Ex. M-C, [REDACTED] Dep. Tr. at  
17 80:22 – 86:2; 94:21 – 95:25).

18           206. [REDACTED]  
19 [REDACTED] Eclipse IVC filter. (Ex. M-D, Mulkey Dep. Tr. at  
20 182:4-8).

21           207. [REDACTED] agreed Ms. Mulkey [REDACTED]  
22 [REDACTED] Eclipse filter [REDACTED]. (Ex. M-C,  
23 [REDACTED] s Dep. Tr. at 85:9-16).

24           208. Ms. Mulkey [REDACTED] Eclipse filter  
25 [REDACTED]. (Ex. M-D, Mulkey Dep. Tr. at 182:9-13).

26           209. Ms. Mulkey [REDACTED] Eclipse filter [REDACTED]  
27 [REDACTED] (Ex. M-D, Mulkey Dep. Tr. at 182:14-16; Ex. M-C, [REDACTED] Dep. Tr. at  
28 83:20 to 84:4).

1           210. Ms. Mulkey [REDACTED] Eclipse filter. (Ex. M-D,  
2 Mulkey Dep. Tr. at 182:18-20).

3           211. Ms. Mulkey [REDACTED]  
4 [REDACTED]. (Ex. M-D, Mulkey Dep. Tr. at 182:21-24).

5           212. Ms. Mulkey [REDACTED]  
6 (Ex. M-D, Mulkey Dep. Tr. at 182:25 to 183:3).

7           213. Ms. Mulkey [REDACTED] Eclipse filter  
8 [REDACTED]. (Ex. M-D, Mulkey Dep. Tr. at 183:4-7).

9           214. Ms. Mulkey [REDACTED] Eclipse filter [REDACTED] (Ex. M-D,  
10 Mulkey Dep. Tr. at 183:8-10).

11           215. [REDACTED] Ms. Mulkey [REDACTED] Eclipse IVC  
12 filter [REDACTED]. (Ex. M-C, [REDACTED]  
13 Dep. Tr. at 82:3-8; 84:5-10).

14           216. [REDACTED] [REDACTED] Ms. Mulkey that her Eclipse IVC filter [REDACTED]  
15 [REDACTED]. (Ex.  
16 M-C, [REDACTED]s Dep. Tr. at 84:11-15).

17           217. [REDACTED] Ms. Mulkey [REDACTED] Eclipse  
18 filter [REDACTED] (Ex. M-C, [REDACTED] Dep. Tr. at  
19 84:17-23).

20           218. [REDACTED] [REDACTED] Ms. Mulkey [REDACTED] Eclipse  
21 [REDACTED] (Ex. M-C, [REDACTED] Dep. Tr. at 84:24 to  
22 85:3).

23           219. [REDACTED] [REDACTED] Ms. Mulkey [REDACTED]  
24 [REDACTED] Eclipse filter [REDACTED]. (Ex. M-C, [REDACTED] Dep. Tr. at  
25 82:9-25).

26           220. [REDACTED] Ms. Mulkey [REDACTED]  
27 [REDACTED] Eclipse filter. (Ex. M-C, [REDACTED] Dep. Tr. at 83: 3-5).  
28

1           221. [REDACTED] Ms. Mulkey [REDACTED]  
2 Eclipse IVC filter [REDACTED] (Ex. M-C, [REDACTED] Dep.  
3 Tr. at 83:6-19).

4           222. If the IFU included pertinent warnings, that is something [REDACTED]  
5 would pass on to his patients. (Ex. M-C, [REDACTED] Dep. Tr. at 106:7-10).

6           223. The Eclipse IFU did not inform [REDACTED] of an increased risk of  
7 movement, migration or tilt with Bard filters versus competitor filters. (Ex. M-C,  
8 [REDACTED] Dep. Tr. at 107:17-21).

9           224. The Eclipse IFU did not inform [REDACTED] of an increased risk of  
10 movement, migration or tilt with Bard optional filters versus Bard permanent filters. (Ex.  
11 M-C, [REDACTED] Dep. Tr. at 107:22 to 108:2).

12           225. The Eclipse IFU did not inform [REDACTED] that the Eclipse had a higher  
13 risk of movement, migration or tilt than any other filter. (Ex. M-C, [REDACTED] Dep. Tr. at  
14 108:3-9).

15           226. If the Eclipse had an increased risk of migration over other filters, that is  
16 something that [REDACTED] would have wanted to know. (Ex. M-C, [REDACTED] Dep. Tr.  
17 at 108:10-15).

18           227. If the Eclipse had an increased risk of migration over other filters, that is  
19 something [REDACTED] would have wanted to know and something he would have taken  
20 into account in his risk benefit analysis on whether to use the filter. (Ex. M-C, [REDACTED]  
21 Dep. Tr. at 108:10-19).

22           228. If the Eclipse had an increased risk of migration over other filters, that  
23 would affect [REDACTED] prescribing habits and, if it was a significant difference, he  
24 wouldn't use the filter. (Ex. M-C, [REDACTED] Dep. Tr. at 108:20 to 109:1).

25           229. [REDACTED] expected Bard to notify him immediately if it was aware of  
26 problems with the design of one of its filters that was causing complications and problems  
27 for patients, or if it was in the process of redesigning its filter to reduce complications.  
28 (Ex. M-C, [REDACTED] Dep. Tr. at 125:2-14). [REDACTED] wanted to know this





1           240. Ms. Mulkey [REDACTED] or her Bard Vena Cava Filter System.  
2 (Ex. M-A, Detailed Bill for Debra Mulkey).

3           241. [REDACTED] ultimately sent Ms. Mulkey [REDACTED].  
4 (Ex. M-C, [REDACTED] Dep. Tr. at 112:1-3).

5           242. [REDACTED], Ms. Mulkey [REDACTED]  
6 [REDACTED] (Ex. M-D, Mulkey Dep. Tr. at 93:1-25).

7           243. Ms. Mulkey [REDACTED]. (Ex. M-D, Mulkey  
8 Dep. Tr. at 94:20-24).

9           244. [REDACTED] Ms. Mulkey [REDACTED]  
10 [REDACTED]. (Ex.  
11 M-I, [REDACTED] Dep. Tr. at 83:13-17).

12           245. According to [REDACTED] medical records, Ms. Mulkey's Eclipse IVC  
13 filter [REDACTED]  
14 [REDACTED] (Ex. M-H, Muehrcke  
15 Report at p. 7).

16           246. Ms. Mulkey did [REDACTED]  
17 [REDACTED]. (Ex. D, Mulkey Dep. Tr. at  
18 142:8-17 and 143: 14-22; Ex. M-E, Plaintiff Fact Sheet of Plaintiff Debra Mulkey  
19 (hereinafter "PFS"), at Section II.13(b) on page 14).

20           247. Ms. Mulkey [REDACTED]. (Ex. M-  
21 D, Mulkey Dep. Tr. at 98:4-6).

22           248. [REDACTED]  
23 [REDACTED] filter. (Ex. M-D, Mulkey Dep. Tr. at 180:11-13).

24           249. [REDACTED]  
25 [REDACTED]. (Ex. M-D, Mulkey Dep. Tr. at 113:12-20).

26           250. In fact, [REDACTED] Ms. Mulkey that IVC filters [REDACTED]  
27 [REDACTED]. (Ex. M-D, Mulkey Dep. Tr. at 137:14-25).

1           251. [REDACTED] did not ever tell Ms. Mulkey that her IVC filter was defective.  
2 (Ex. M-C, [REDACTED] Dep. Tr. at 115:19-21).

3           252. [REDACTED] did not ever tell Ms. Mulkey that the manufacturer of the IVC  
4 filter had injured her or caused her harm. (Ex. M-C, [REDACTED] Dep. Tr. at 115:22-25).

5           253. [REDACTED] did not ever tell Ms. Mulkey that her IVC filter was unsafe.  
6 (Ex. M-C, [REDACTED] Dep. Tr. at 116:1-3).

7           254. [REDACTED] Ms. Mulkey did  
8 not believe she had been injured. (Ex. M-D, Mulkey Dep. Tr. at 179:21 – 180:1).

9           255. [REDACTED] Ms. Mulkey did  
10 not believe there was anything defective about her filter. (Ex. M-D, Mulkey Dep. Tr. at  
11 180:2-5).

12           256. [REDACTED] Ms. Mulkey did  
13 not believe she had been wronged by the manufacturer of the IVC filter, Bard. (Ex. M-D,  
14 Mulkey Dep. Tr. at 180:5-10).

15           257. [REDACTED] Ms. Mulkey [REDACTED]  
16 [REDACTED] Bard IVC filter. (Ex. M-D, Mulkey Dep. Tr. at  
17 147:23-148:4).

18           258. [REDACTED] Ms. Mulkey [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED] IVC filters. (Ex. M-D, Mulkey Dep. Tr. at 185:3-14).

22           259. In the fall of 2015, Ms. Mulkey saw an ad on TV about IVC filters. (Ex.  
23 M-D, Mulkey Dep. Tr. at 57:23 to 58:2).

24           260. When Ms. Mulkey saw the Internet and television ads in October 2015, this  
25 caused her to be concerned about her filter. (Ex. M-D, Mulkey Dep. Tr. at 138:14-20).

26           261. It was in late 2015 when Ms. Mulkey first realized that she may have been  
27 wronged by Bard and may have a lawsuit. (Ex. M-D, Mulkey Dep. Tr. at 180:21 –  
28 181:2).

1           262. When Ms. Mulkey saw the ad on TV in October 2015, that's when she  
2 realized that not being able to remove her IVC filter was the result of a defect in the IVC  
3 filter. (Ex. M-D, Mulkey Dep. Tr. at 144:19-145:3).

4           263. Due to the inadequate design of Ms. Mulkey's Bard Eclipse IVC filter, [REDACTED]  
5 [REDACTED]  
6 [REDACTED] (Ex. M-H,  
7 Muehrcke Report at p. 7; Ex. M-B, Hurst Report at pp. 5-7, 12).

8 **IV. FACTS RELATED TO JONES V. BARD**

9           A. Implantation Facts

10           264. [REDACTED], Doris Jones [REDACTED]  
11 [REDACTED]  
12 [REDACTED] Jones Medical Records, attached as  
13 Exhibit J-A, at DORISJONES000004.

14           265. [REDACTED]  
15 [REDACTED] *Id.* at DORISJONES000021.

16           266. [REDACTED]  
17 [REDACTED]. *Id.* at DORISJONES000002.

18           267. [REDACTED]  
19 [REDACTED] *Id.* at DORISJONES000026.

20           268. [REDACTED]  
21 [REDACTED]  
22 [REDACTED]. *Id.*

23           269. [REDACTED]  
24 [REDACTED]. Transcript of  
25 Deposition of [REDACTED] ("[REDACTED]"), attached as Exhibit J-B, at 50:15-51:16.

26           270. [REDACTED]. Jones  
27 Consent Form Dated [REDACTED], attached as Exhibit J-C, at  
28 JONESD [REDACTED]; [REDACTED] Dep, Exhibit J-B, at 55:14.

1 271. [REDACTED] implanted a Bard Eclipse IVC filter in Doris [REDACTED]  
 2 Exhibit J- A at DORISJONES000026 - 000027; [REDACTED] Dep, Exhibit J-B, at 59:2-11.

3 272. Doris Jones [REDACTED] Eclipse IVC  
 4 filter [REDACTED]. Bard Peripheral Vascular's Supplemental Responses to  
 5 Plaintiffs Doris and Alfred Jones's First Set of Requests for Admissions to Bard  
 6 Peripheral Vascular, Inc., attached as Exhibit 116 hereto, at 8, supplemental response to  
 7 RFA 13.

8 273. The Eclipse is a "retrievable" IVC filter, meaning that while the Eclipse can  
 9 be removed if clinically necessary or appropriate; Bard promotes the filter as safe for  
 10 permanent implantation. Eclipse Vena Cava Filter, Femoral Vein Approach, Instructions  
 11 for Use ("Eclipse IFU"), attached as Exhibit 117, at BPV-17-01-00142881; *see also*  
 12 Exhibit D at 5, supplemental response to RFA 7.

13 274. [REDACTED]  
 14 [REDACTED]. [REDACTED] Dep, Exhibit J-B,  
 15 at 54:3-13.

16 275. At the time, Bard's SNF was available on the market for implantation as a  
 17 permanent IVC filter.

18 B. [REDACTED] Was Familiar with Bard's IVC Filter  
 19 W ones's Eclipse IVC Filter.

20 276. [REDACTED] did not recall reading the Eclipse IFU, but he had read IFUs for  
 21 IVC filters:

22 Q. And do you read the IFU?

23 A. Sometimes. I mean, I have read them. I don't -- certainly don't  
 24 read them on every package, because they're the same from the same device,  
 25 but -- you know, not -- not all the time, but it does come up, for example, at  
 26 meetings, or you're reading about and someone's discussing an issue with an  
 27 IFU. You know, if something is within the IFU or not, to help define things  
 28 that might be outside of the IFU but still medically indicated.

Q. Do you know if you ever read the IFU for the Eclipse IVC filter?

A. Not that I recall.

Q. Okay. And IFUs have warnings on them of side effects,  
 complications, things like that, also?

A. Yes.

1 Q. And even if you haven't read the Eclipse IFU, you're probably generally  
 2 familiar with IVC filter IFUs, if they warn of things like fractures,  
 migration, perforation, tilt; complications like that. Right?

3 A. Yes. Yes.

4 [REDACTED] Dep, Exhibit J-B, at 47:11-48:7.

5 277. [REDACTED] and his practice have "predominantly" used the Bard IVC filters.

6 *Id.* at 33:21-34:6.

7 278. Significantly, the Eclipse IFU warnings are the same as those in the G2 and  
 8 G2X. As between the Eclipse IFU and the G2X IFU, with two exceptions,<sup>1</sup> the only  
 9 difference between the two documents is the use of the terms "Eclipse" in one and "G2X"  
 10 in the other. See Exhibit J-E; G2X Vena Cava Filter, Femoral Vein Approach,  
 Instructions for Use ("G2X IFU"), attached as Exhibit J-G.

11 279. Under the heading "Warnings," both the G2X IFU and Eclipse IFU state:

12 11. Filter fractures are a known complication of vena cava filters.  
 13 There have been some reports of serious pulmonary and cardiac  
 14 complications with vena cava filters requiring the retrieval of the fragment  
 utilizing endovascular and/or surgical techniques.

15 12. Movement, migration or tilt of the filter are known complications  
 16 of vena cava filters. Migration of filters to the heart or lungs has been  
 17 reported. There have also been reports of caudal migration of the filter.  
 Migration may be caused by placement in IVCs with diameters exceeding  
 the appropriate labeled dimensions specified in this IFU. Migration may  
 also be caused by improper deployment, deployment into clots and/or  
 dislodgement due to large clot burdens.

18 ...  
 19 See Potential Complications section for further information regarding other  
 known filter complications.

20 Exhibit J-E at BPV-17-01-00142881; Exhibit J-G at BPV-17-01-00137404.

21 280. The G2 IFU states under "Warnings":

22 8. Filter fractures are a known complication of vena cava filters.  
 23 There have been some reports of serious pulmonary and cardiac  
 24 complications with vena cava filters requiring the retrieval of the fragment  
 utilizing endovascular and/or surgical techniques.

25 9. Movement, migration or tilt of the filter are known complications  
 of vena cava filters. Migration of filters to the heart or lungs has been

26 <sup>1</sup> The two other differences are: (1) the G2X IFU names one section as "MRI Safety"  
 27 whereas the Eclipse IFU names the section "MRI Information"; and (2) In the section  
 28 "Directions for Use," the two IFUs use different terminology in step 14 (which is utterly  
 unrelated to warnings and complications). See Exhibit J-G at BPV-17-01-00137403,  
 00137406; Exhibit J-E at BPV-17-01-00142880, 00142883.

reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.

See Potential Complications section for further information regarding other known filter complications.

G2 Filter System, Femoral Vein Approach, Instructions for Use, (“G2 IFU”), attached as Exhibit J-H, at BPV-17-01-00118398.

281. Under the heading “Potential Complications,” the G2 IFU, G2X IFU, and Eclipse IFU all state:

- Movement, migration or tilt of the filter are known complications of vena cava filters. Migration of filters to the heart or lungs has been reported. There have also been reports of caudal migration of the filter. Migration may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in this IFU. Migration may also be caused by improper deployment, deployment into clots and/or dislodgement due to large clot burdens.

- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.

All of the above complications may be associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

Exhibit J-E at BPV-17-01-00142882; Exhibit J-G at BPV-17-01-00137405; Exhibit J-H at BPV-17-01-00118399.

282. Under the heading “Clinical Experience,” the G2 IFU, G2X IFU, and Eclipse IFU all reference and contain identical information regarding a clinical study involving 100 patients to assess the safety of removal of the G2 Filter. Exhibit J-H at BPV-17-01-00118400; Exhibit J-G at BPV-17-01-00137406 - 00137407; Exhibit J-E at BPV-17-01-00142883.

283. [REDACTED] was aware that fracture was a possible complication of IVC filters. [REDACTED] Dep, Exhibit J-B, at 48:2-7.



1           284. [REDACTED] knew the G2 had problems with migrations and fractures. *Id.* at  
2 40:18-21.

3           C. [REDACTED] Was Not Aware of Adverse Information Regarding the Rates and  
4 F of Complications of Bard's IVC Filters That Bard Did Not  
5 Report to Him.

6           285. [REDACTED] was not aware of specific rates of fracture for IVC filters for Bard  
7 or other manufacturers. *Id.* at 62:24-64:7.

8           286. [REDACTED] understanding at the time was that the rates were very low but  
9 then within the last four years or so [REDACTED] [REDACTED] learned that  
10 they were higher. *Id.* at 64:8-17.

11           D. [REDACTED] Would Have Wanted to Know if Bard's IVC Filter Fracture Rates  
12 a Complication Rates Were Greater Than Those of Its Competitors.

13           287. [REDACTED]  
14 [REDACTED] *Id.* at  
15 48:20-49:4.

16           288. Since then, [REDACTED] has learned more about IVC filters and their  
17 complications. *Id.* at 49:5-9.

18           289. [REDACTED] would have wanted to know before he implanted the Eclipse IVC  
19 in Doris Jones what Bard knew about complications with its IVC filters. *Id.* at 49:10-14.

20           290. [REDACTED] testified that he would have wanted to know if the fracture rates  
21 for the Recovery, a predicate device for the Eclipse, exceeded the fracture rates of IVC  
22 filters from other manufacturers. *Id.* at 81:13-24.

23           291. [REDACTED] admitted that "[a]ll of the fracture information rate [for Bard's  
24 IVC filters] is something that was important to consider in the decision [to use Bard IVC  
25 filters]." *Id.* at 89:20-22.

26           292. [REDACTED] testified that it would have been important to him to know that  
27 the Recovery filter had reporting rates for death, filter migration, IVC perforation, and  
28 filter that were substantially higher than all other filters. *Id.* at 82:14-24.

1           293. [REDACTED] believed that comparative information as between filters was  
2 important: “all information is helpful, if there’s -- if it is information regarding concern  
3 about one filter being better than the other.” *Id.* at 90:19-22.

4           294. [REDACTED] also testified he would expect a medical device company to  
5 report to doctors when the company learns that its device is less safe than alternative  
6 treatments or other alternative products. *Id.* at 21:2-9.

7           295. [REDACTED] testified he would need to know that information to make  
8 informed decisions about using products. *Id.* at 21:10-13.

9           296. [REDACTED] testified that patients cannot make informed-consent decisions if  
10 the doctors do not receive the information to inform them. *Id.* at 21:14-18.

11           E. [REDACTED]

12           297. [REDACTED].

13 Exhibit J-A at DORISJONES000104 – 000105.

14           298. [REDACTED]

15 [REDACTED]. *Id.* at  
16 DORISJONES000073.

17           299. [REDACTED]

18 [REDACTED]  
19 [REDACTED] Transcript of deposition of [REDACTED], [REDACTED], attached as Exhibit J-I, at  
20 44:12-23 ([REDACTED]);  
21 47:2-15.

22           300. [REDACTED]

23 [REDACTED].  
24 Exhibit J-A at DORISJONES000096.

25           301. [REDACTED]

26 [REDACTED]. *Id.* at DORISJONES000096.  
27  
28

1           302. [REDACTED]  
2           [REDACTED]. Transcript of deposition of [REDACTED]  
3           [REDACTED], attached as Exhibit J-J, at 25:7-24.  
4           303. [REDACTED]  
5           [REDACTED]. *Id.* at  
6           46:13-47:21.  
7           304. [REDACTED]  
8           [REDACTED] Exhibit J-A at  
9           DORISJONES000073.  
10          305. [REDACTED]  
11          [REDACTED]. *Id.* at DORISJONES000104 –  
12          000105.1  
13          306. [REDACTED]  
14          [REDACTED]. *Id.* at DORISJONES000073.  
15          307. Plaintiffs’ experts have subsequently determined that Doris’s Filter [REDACTED]  
16          [REDACTED]. Transcript of deposition of Dr. Darren  
17          Hurst, Aug. 19, 2016, at 55:7-10 ([REDACTED] G2 devices);  
18          excerpts of Report of Robert McMeeking, PhD on Bard Inferior Vena Cava Implanted in  
19          Mrs. Doris Jones, June 9, 2017, attached as Ex. J-K, at 2; excerpts of Expert Report of  
20          Darren R. Hurst, M.D., dated June 2, 2017, attached as Ex. J-L, at 10; excerpts of Report  
21          of Robert Muehrcke, M.D., dated June 6, 2017, attached as Ex. J-M, at 1.  
22          308. In December 2005, internal Bard reports determined that the “reported rate  
23          of fractures [was] judged to be serious (Critical R002 rating).” Email from G. Schultz to  
24          K. Shifrin and J. Hudnall dated Dec. 19, 2005, BPVEFILTER-01-00002447, attached as  
25          Ex. J-N.  
26          309. Plaintiffs’ physician experts have testified that information regarding  
27          complication rates and comparative complication rates is important to treating physicians  
28          to determine the risk/benefit of using the device and in order to obtain appropriate

1 informed consent from patients. Transcript of deposition of Dr. Kinney, July 17, 2017,  
2 attached as Ex. J-O, at 39:18-40:20, 101:21-102:18, 191:4-13, 193:8-25, 196:1-10, 204:7-  
3 205:3, 231:25-232:23; transcript of deposition of Dr. Roberts, July 7, 2017, attached as  
4 Ex. J-P, at 210:22-214:15, 237:15-238:14, 240:1-25. 294:9-295:9, 296:6-19.

5 310. Bard's expert, Dr. Mark Moritz, agreed that a medical doctor would want to  
6 know from a medical device company the type of information contained in Bard's internal  
7 documents that spoke to serious injuries and death caused by failure modes of the Bard  
8 filters. Transcript of deposition of Mark Moritz, M.D., July 18, 2017, attached as Ex. J-Q,  
9 at 85:12-86:3.

10 **V. ADDITIONAL FACTS**

11 311. Bard's labeling and marketing materials represent that the G2 Filter was  
12 safe and effective for permanent implantation in the human body for the prevention of  
13 pulmonary embolism. Ex. 63, BPV-17-01-00137389; G2 IFU, attached as Exhibit 118,  
14 BPV-17-01-00118398; G2 IFU, attached as Exhibit 119, BPV-17-01-00137437.

15 312. Bard represented to the FDA that the "Design, material, components,  
16 fundamental technology and intended use" of the G2 were substantially equivalent to the  
17 predicate device, the Recovery Filter. Letter from FDA to Bard re marketing of G2 Filter,  
18 attached as Exhibit 120, K050558.

19 313. Bard further represented that no material changes or additional components  
20 had been incorporated in the G2 Filter from the Recovery Filter and that modifications  
21 were just dimensional changes. Ex. 120, K050558.

22 314. Bard's internal documents reveal (after the G2 was FDA-cleared) that while  
23 pertinent safety data was not revealed to FDA regarding migration resistance, BARD  
24 continued to discuss its competitive activity including that the Recovery Filter was still  
25 being placed in patients and the most probable Medicare codes that return payment for  
26 placement of the BARD devices were exchanged. Email from J. Greer to J. Hudnall dated  
27 7/22/2005, BPVE-01-001797300, attached as Exhibit 121.  
28

1 RESPECTFULLY SUBMITTED this 13<sup>th</sup> day of October, 2017.

2 GALLAGHER & KENNEDY, P.A.

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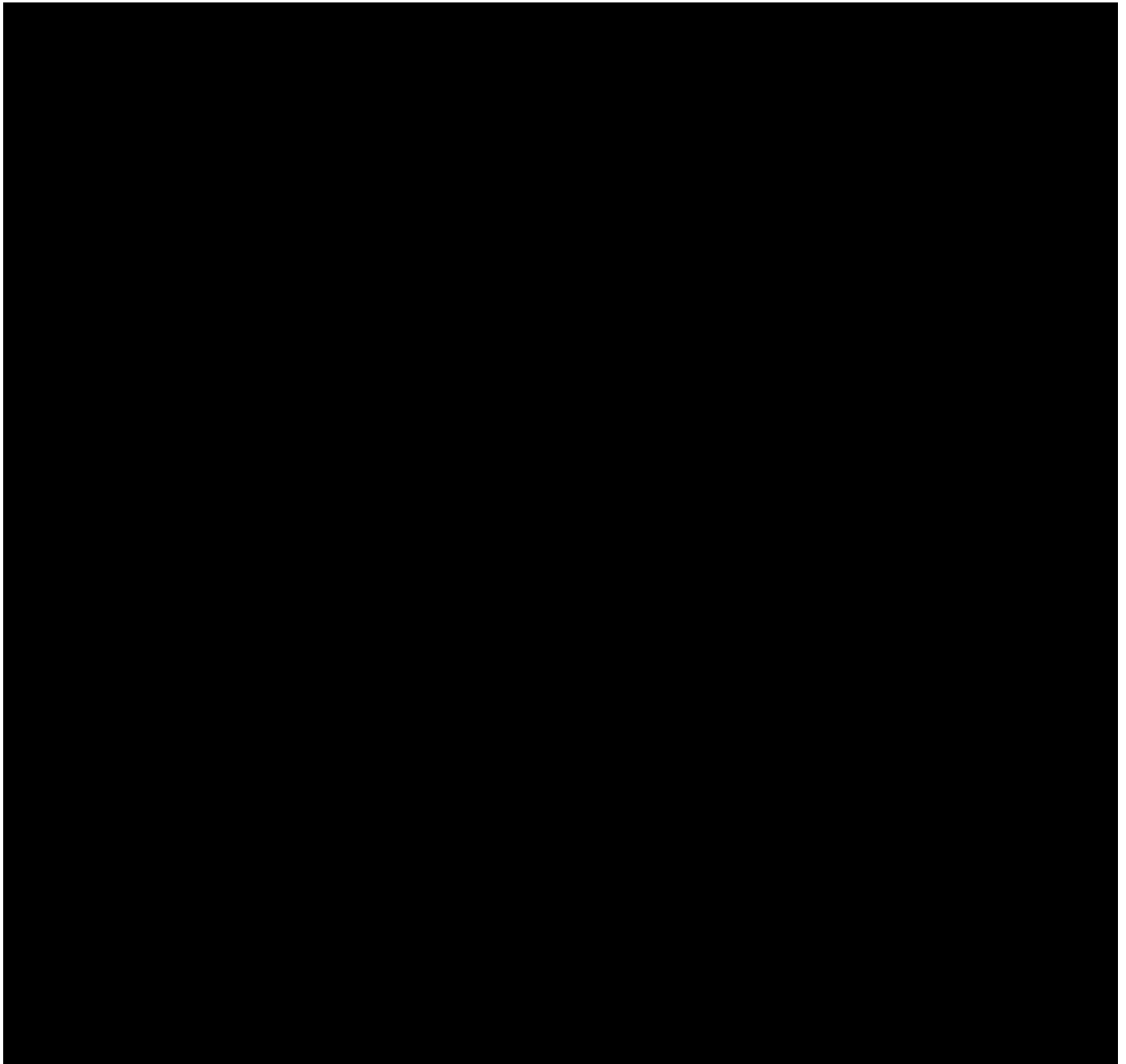
13 **CERTIFICATE OF SERVICE**

14 I hereby certify that on this 13<sup>th</sup> day of October, 2017, I electronically transmitted  
15 the attached document to the Clerk's Office using the CM/ECF System for filing and  
16 transmittal of a Notice of Electronic Filing.

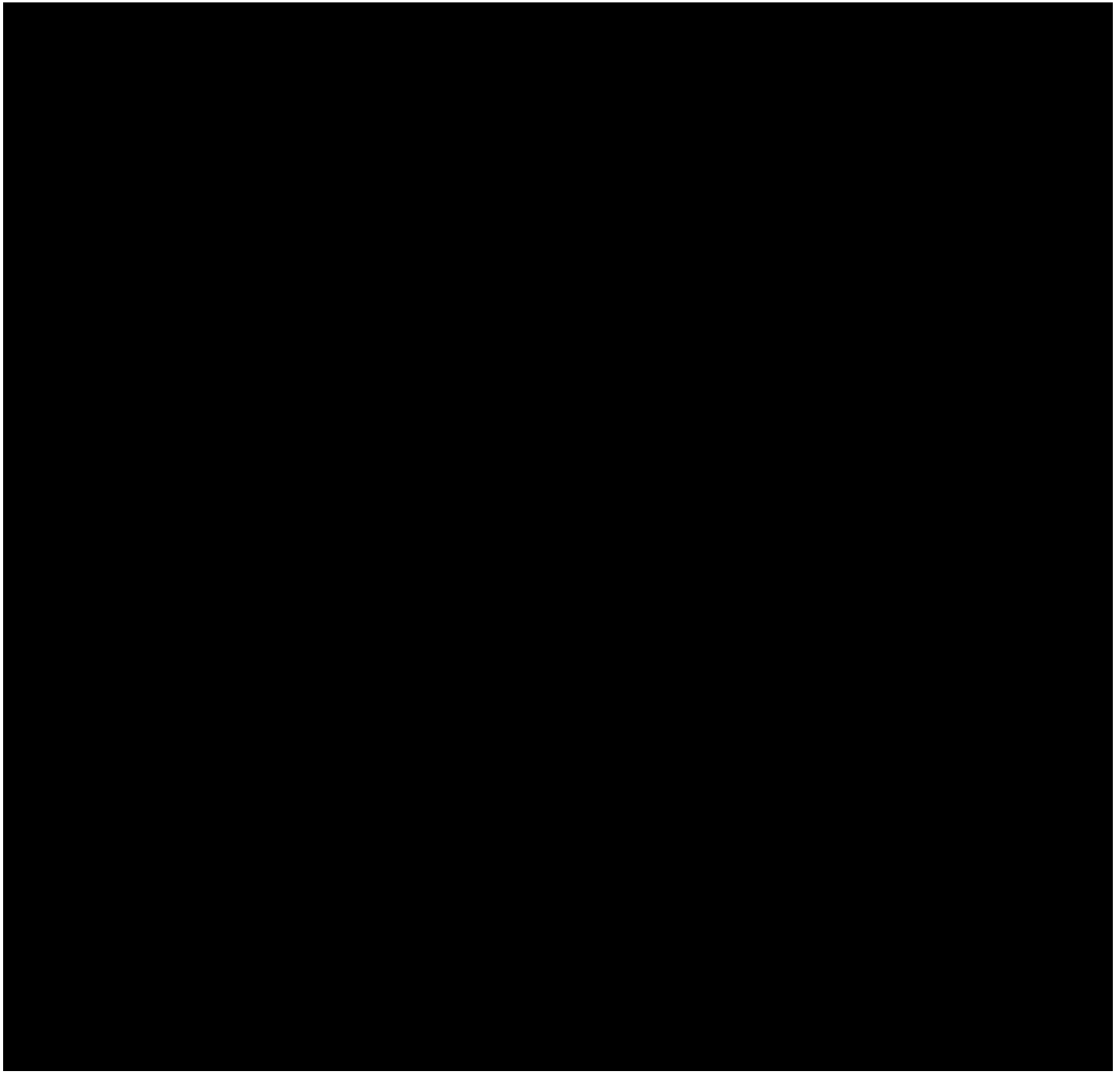
17 /s/ Gay Mennuti

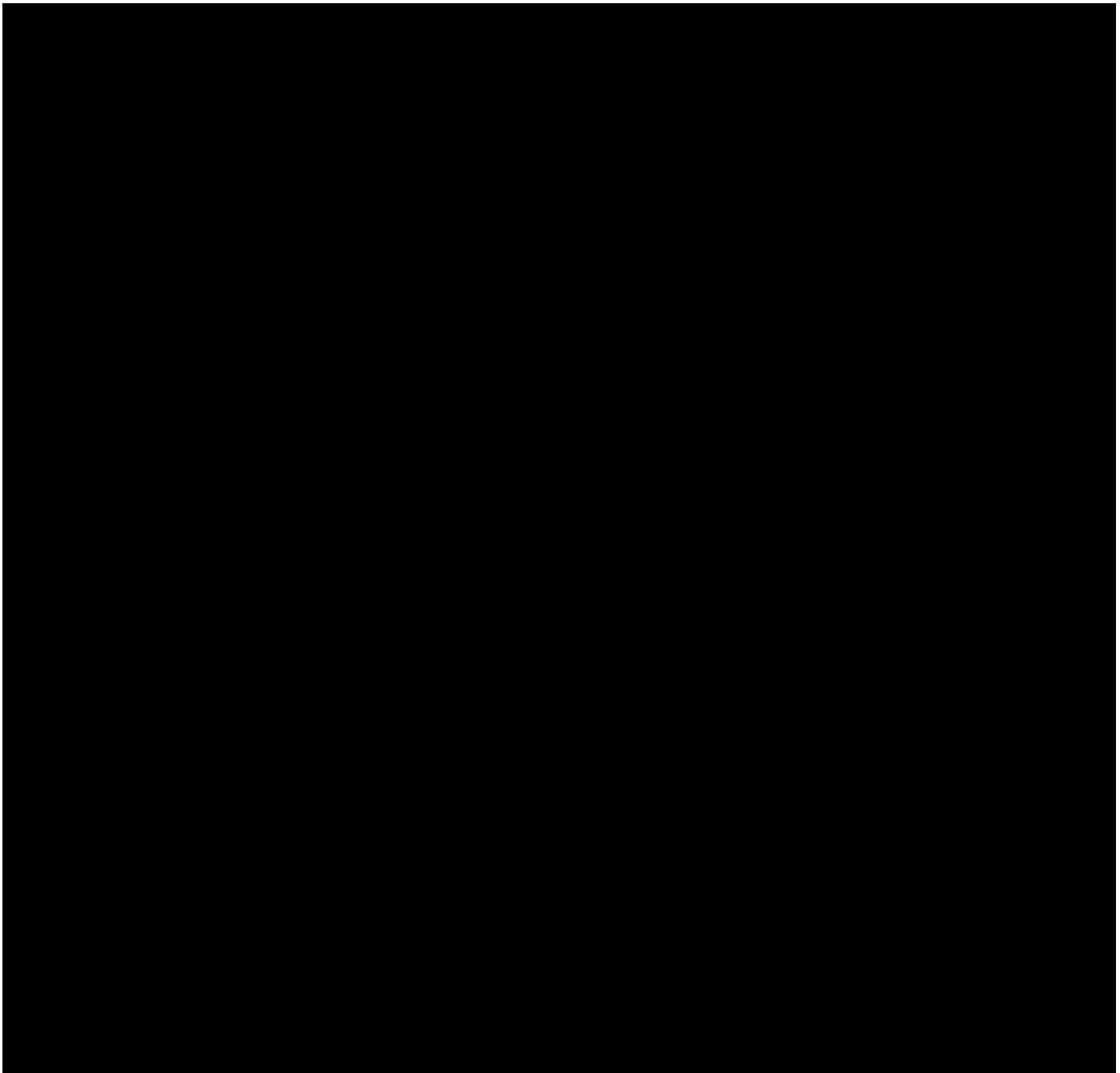
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TO DOCKET 8186**

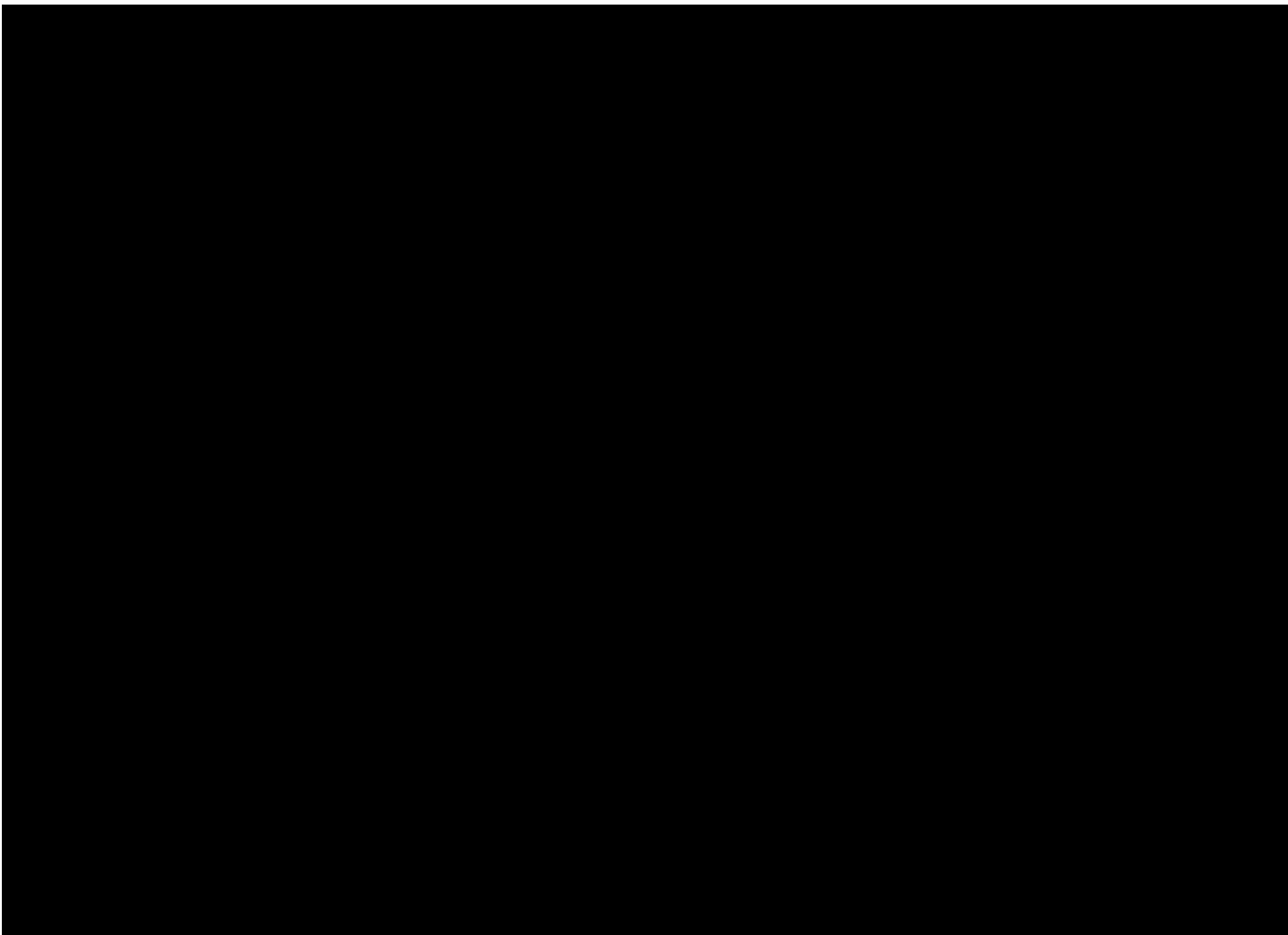
**Exhibit H-A - REDACTED**

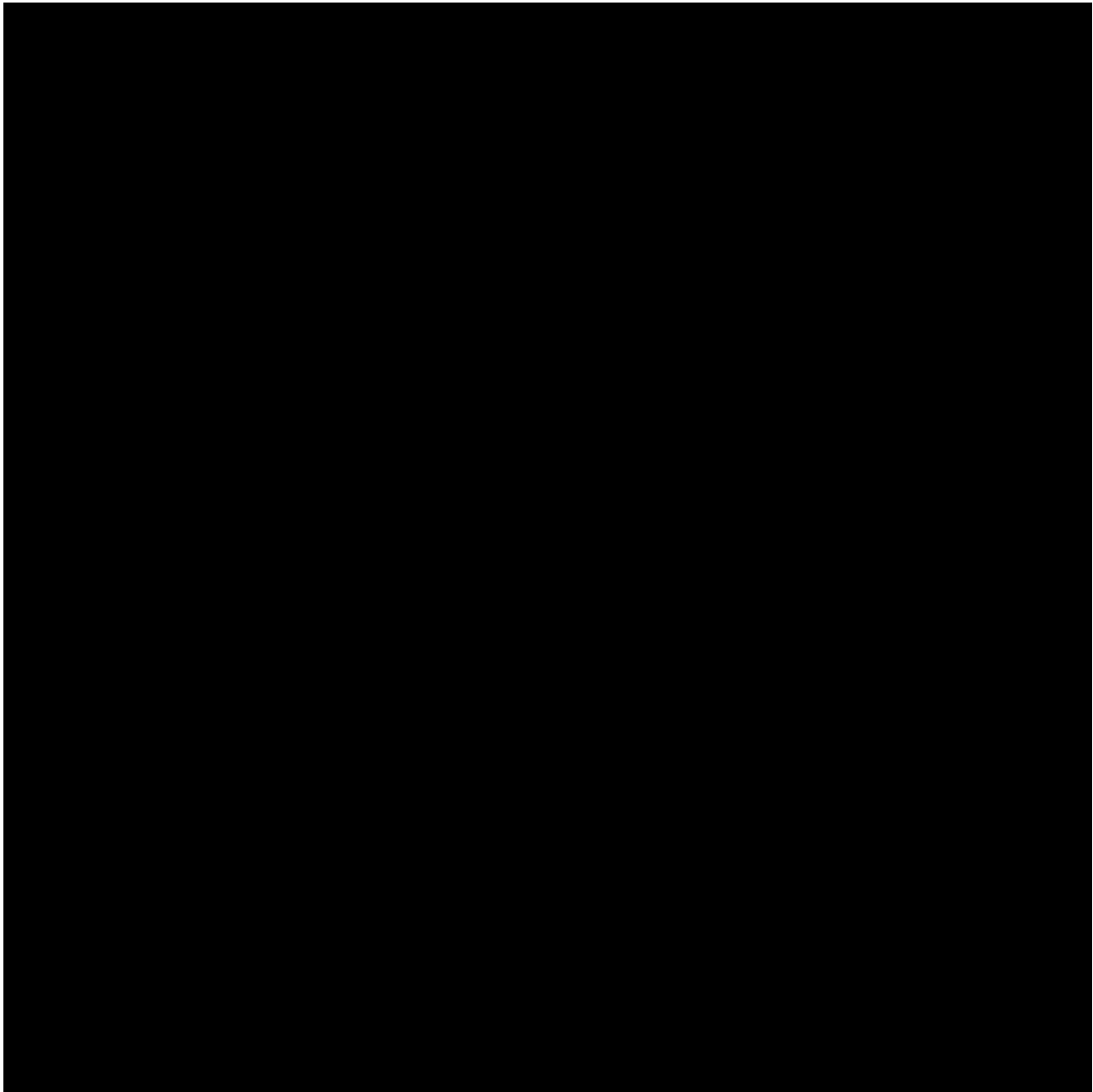


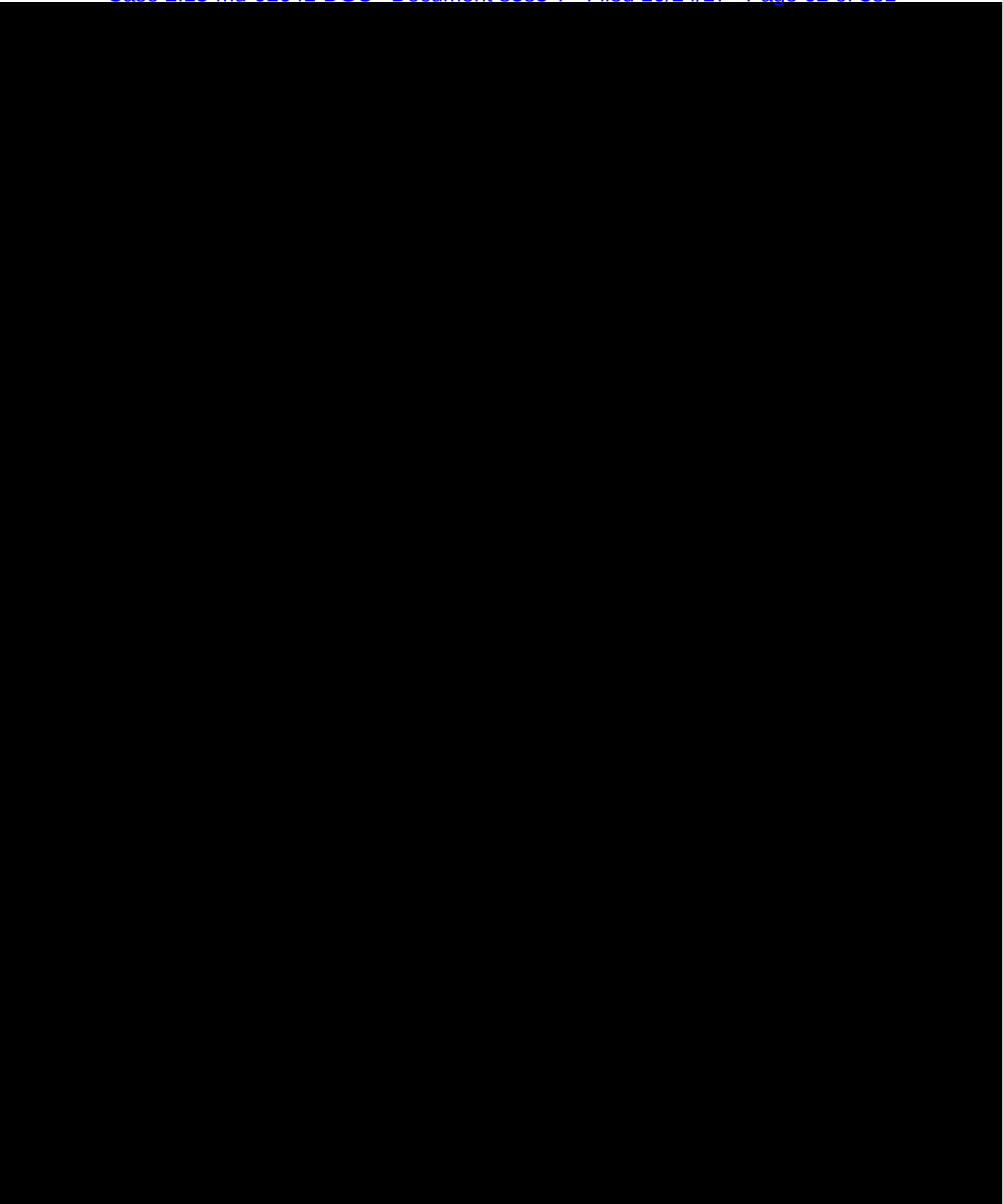


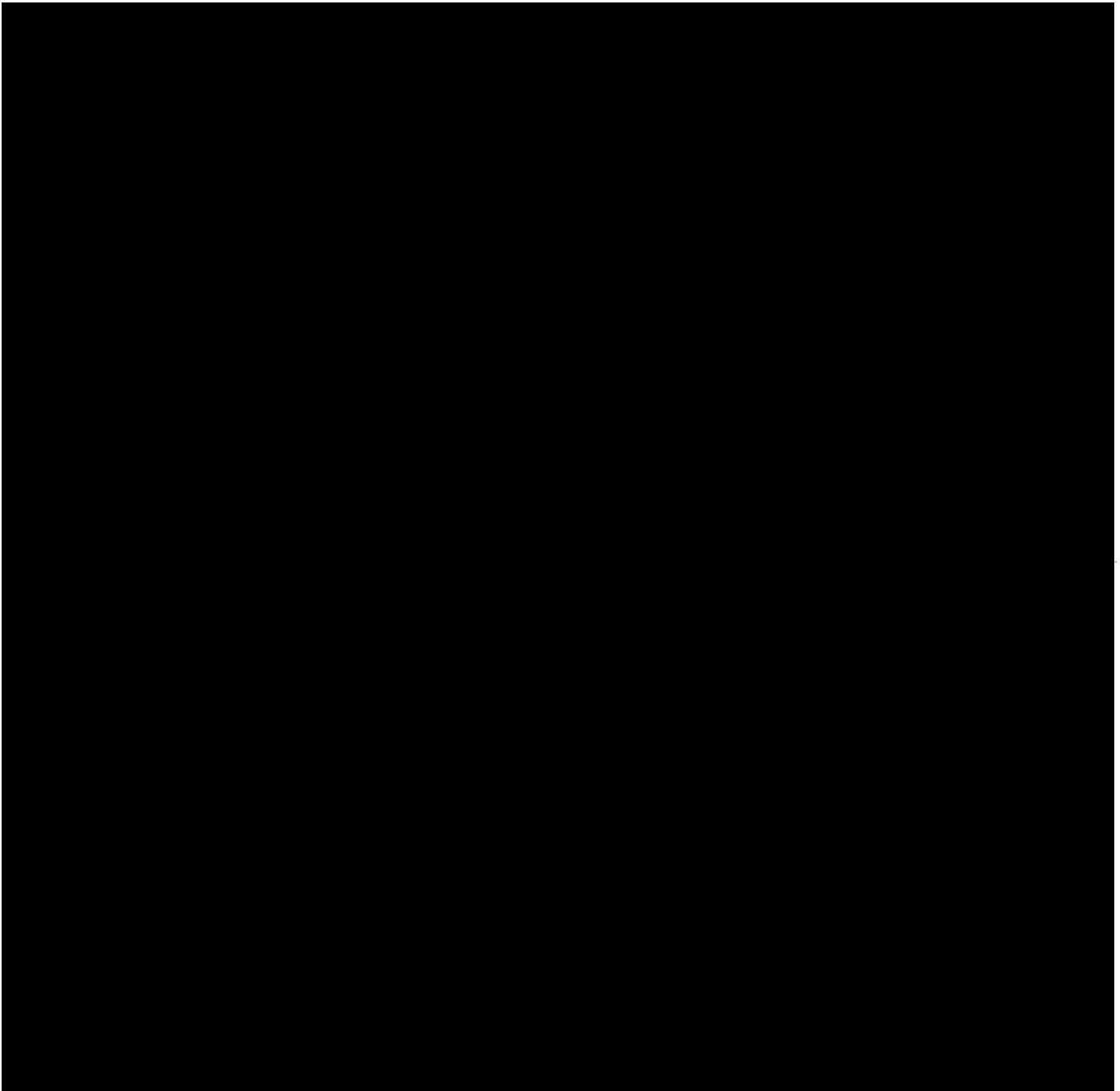


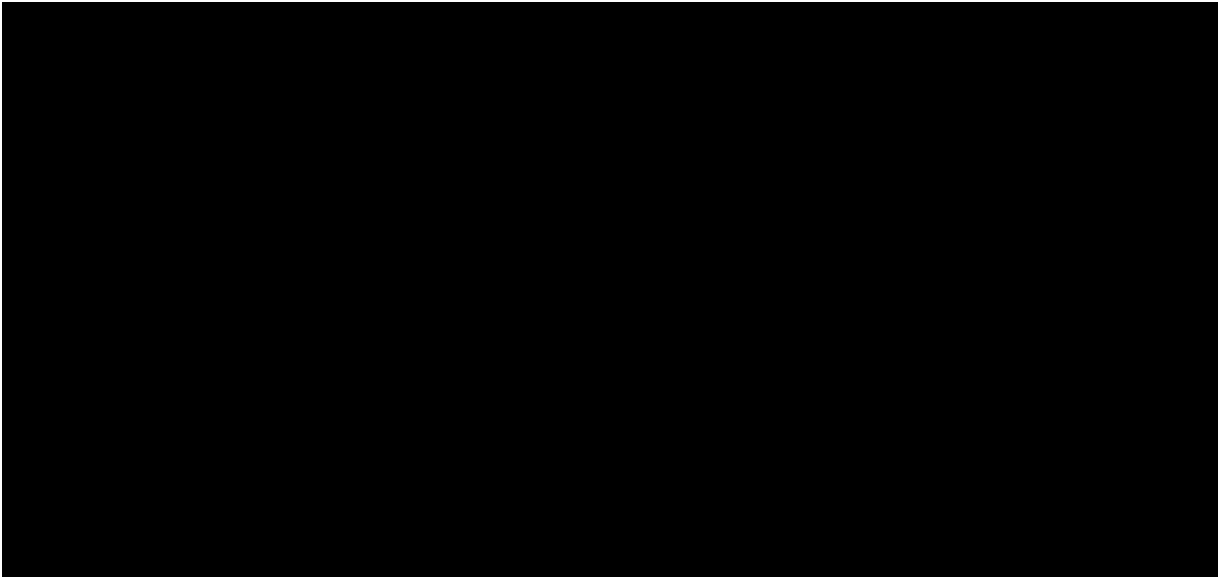




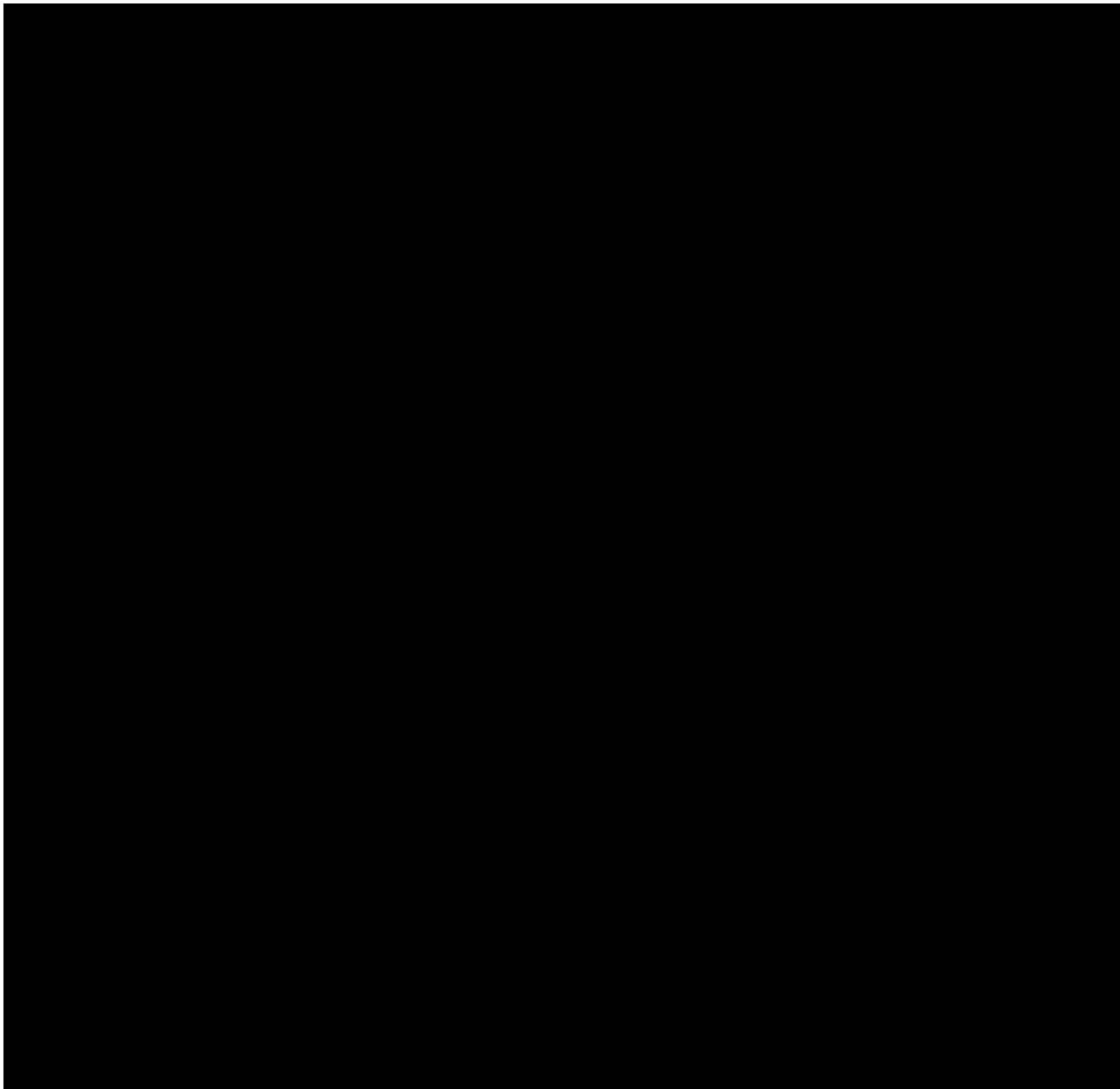


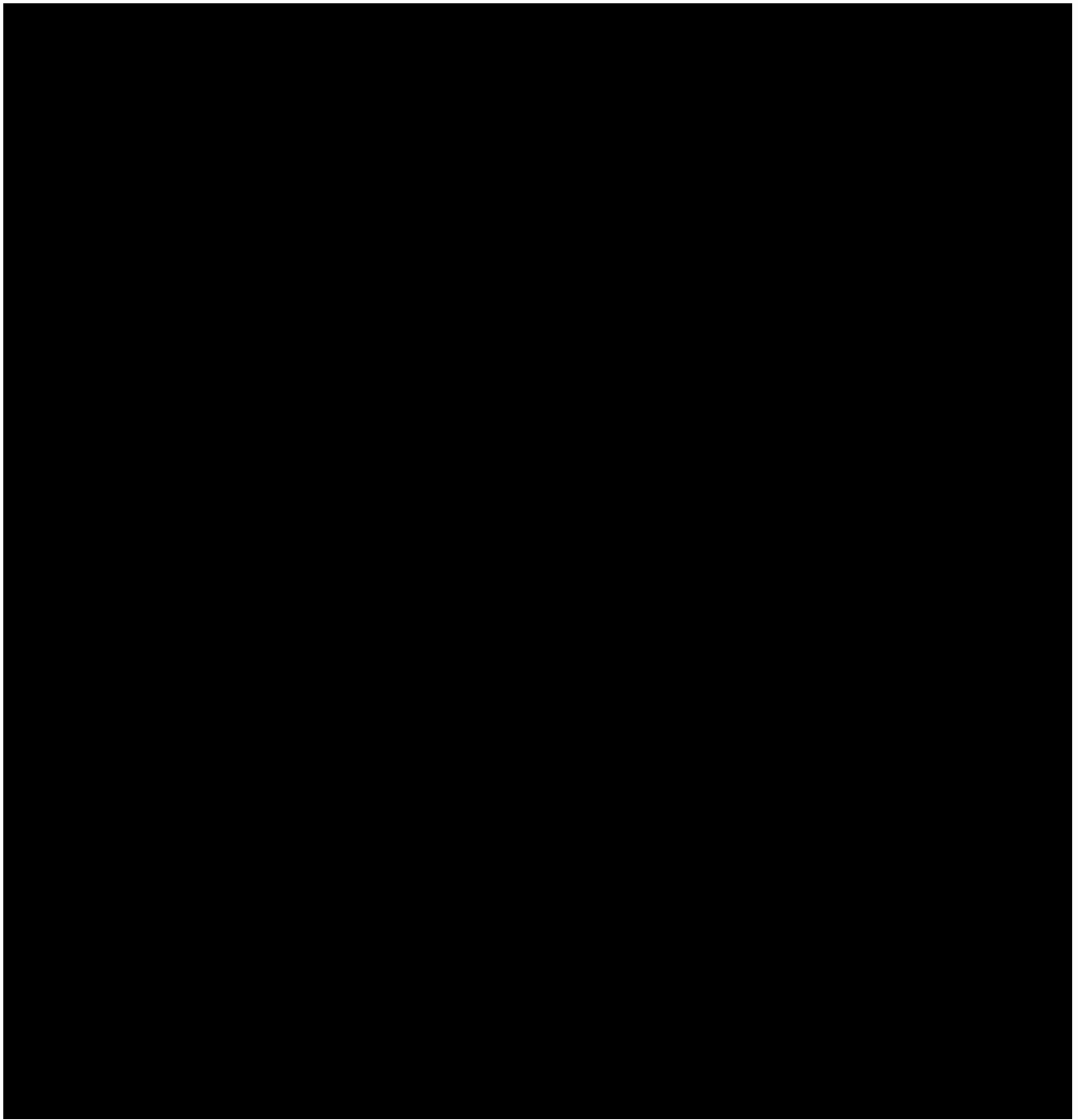




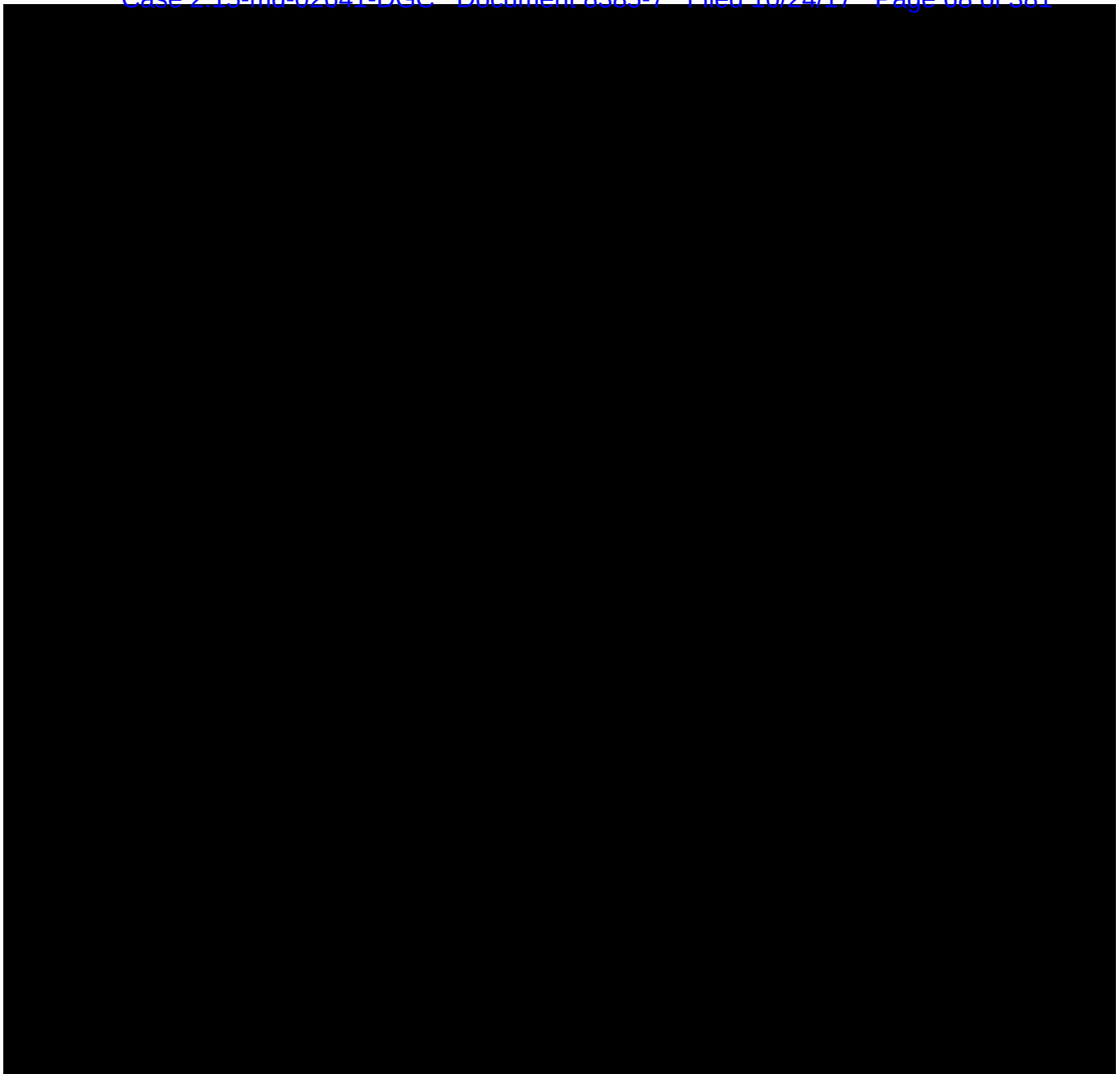


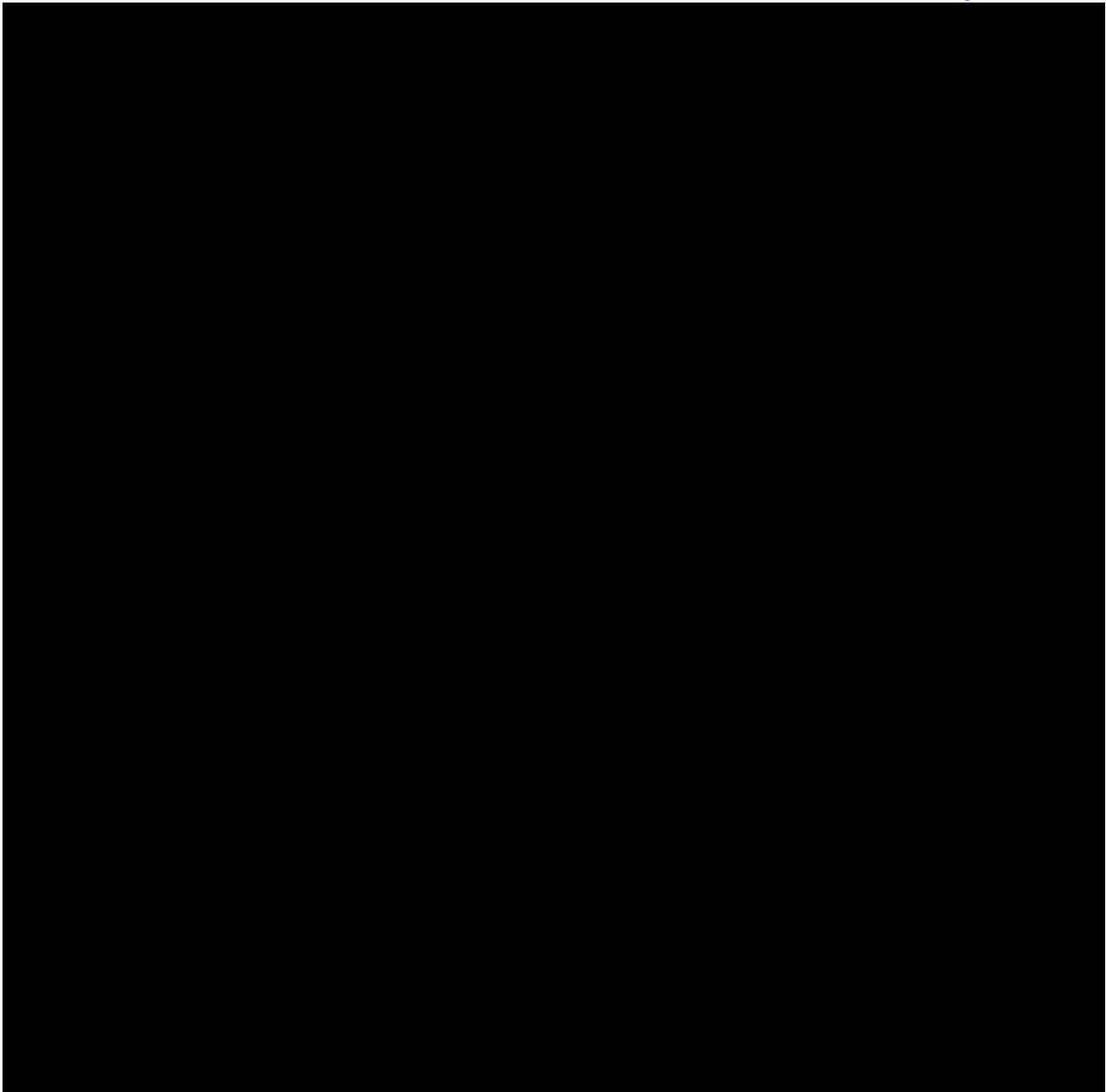


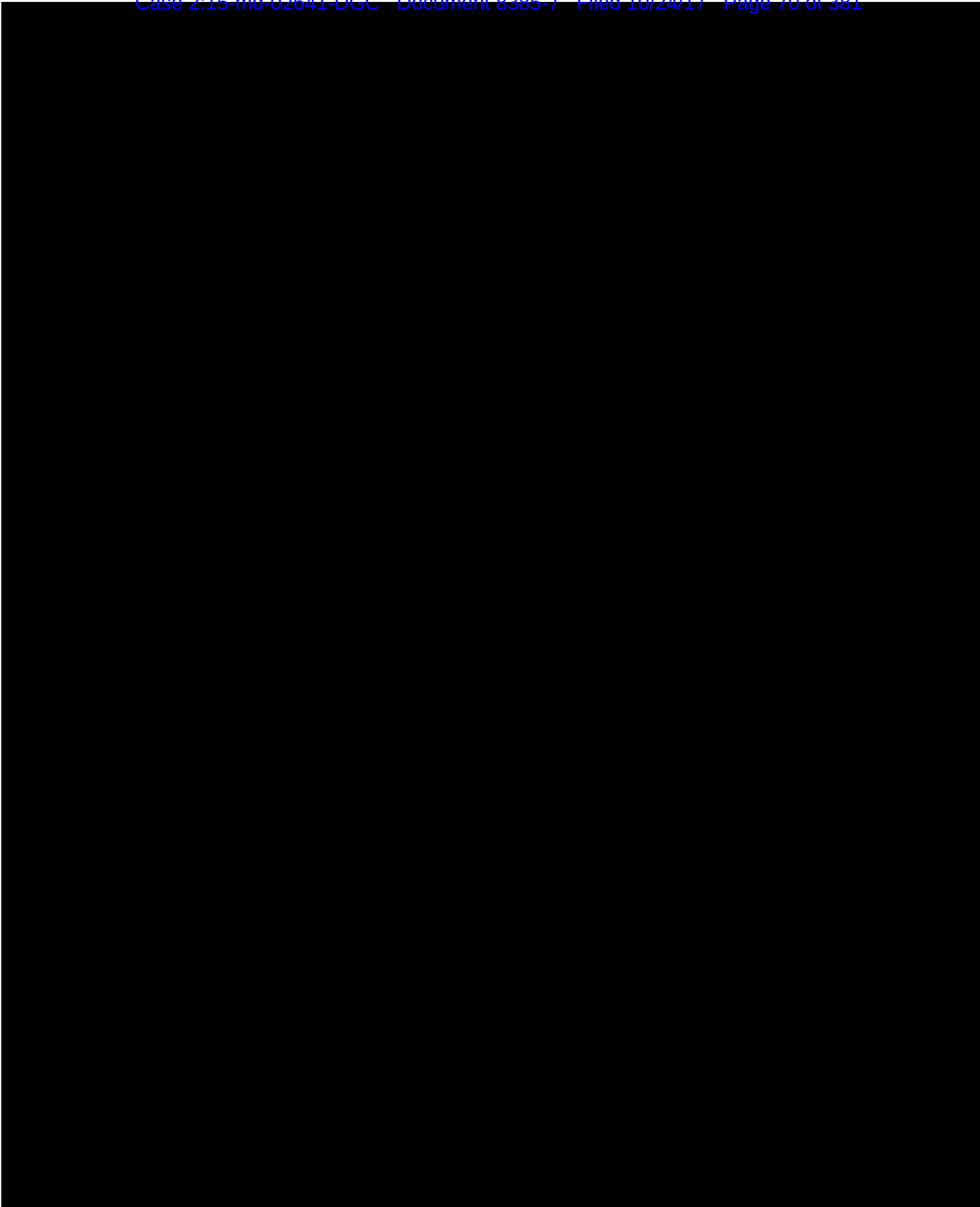


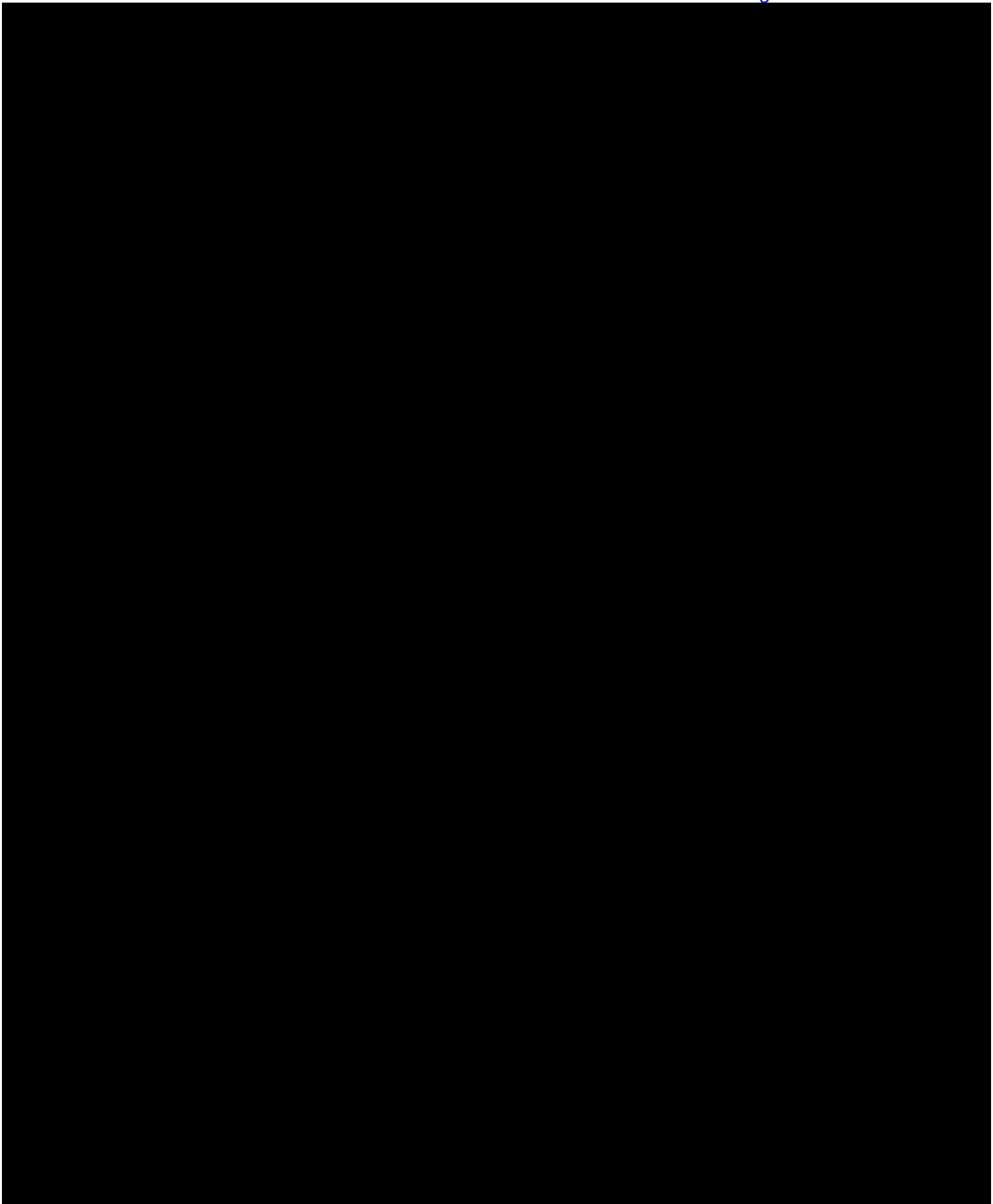


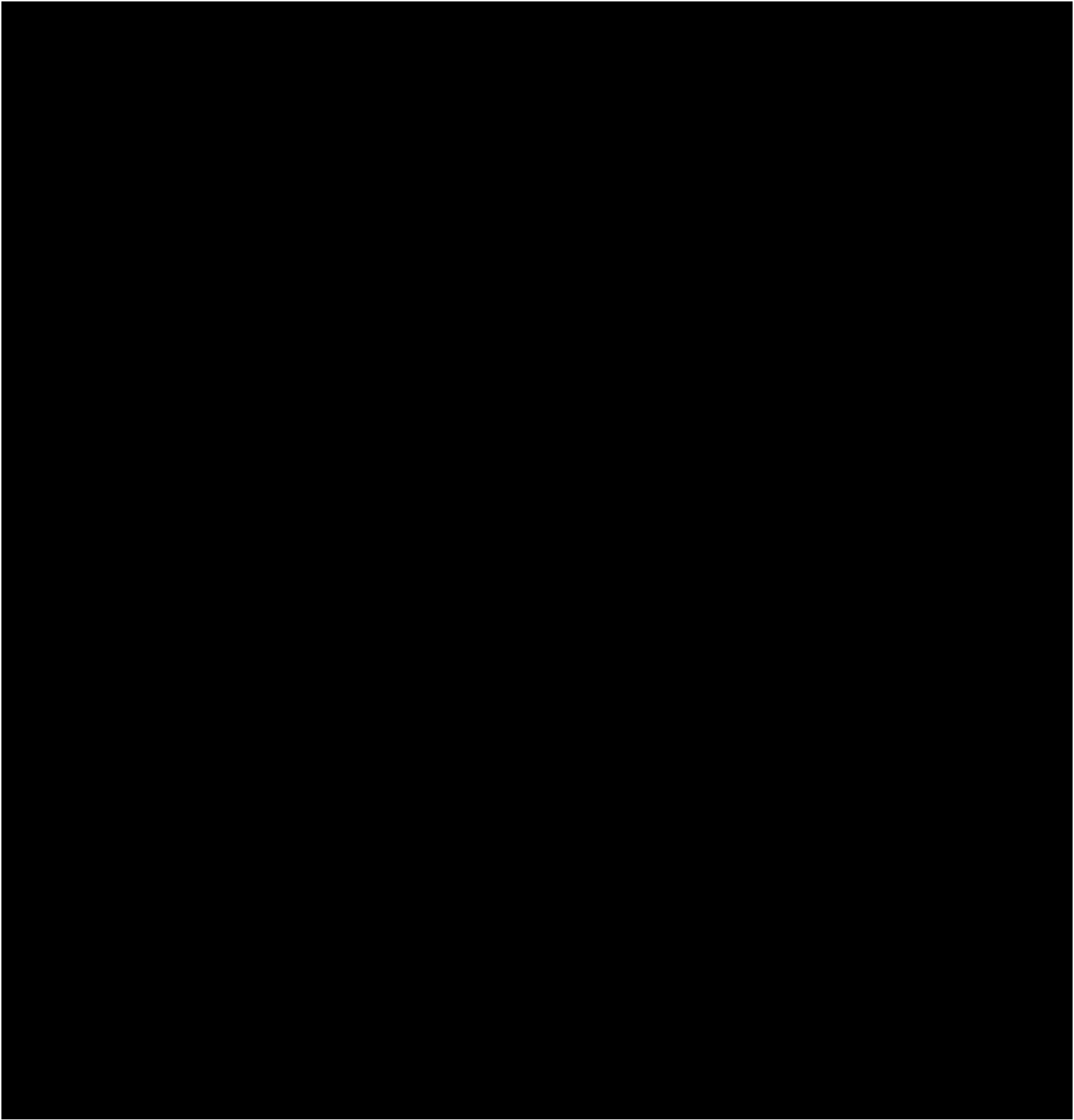




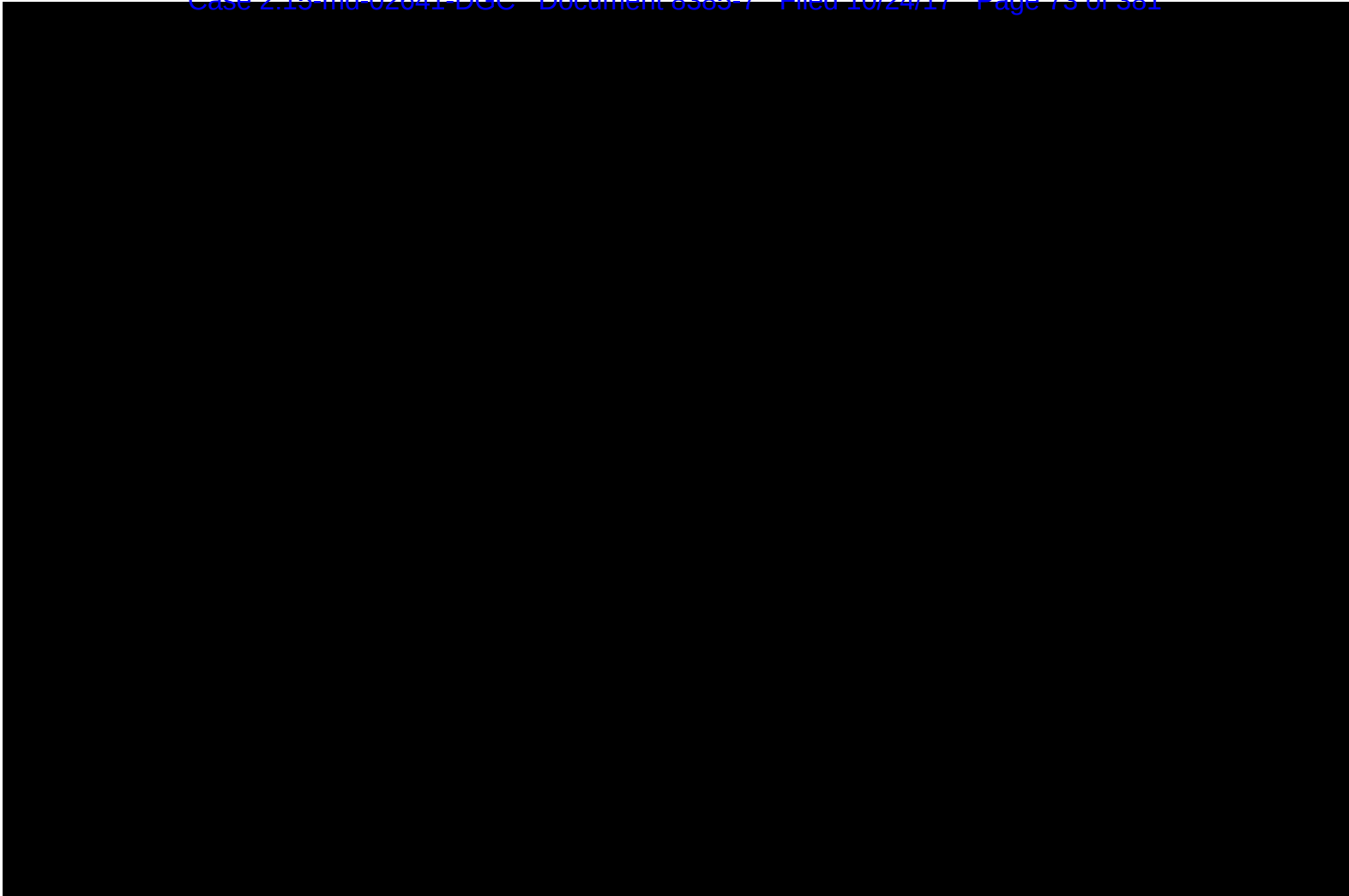


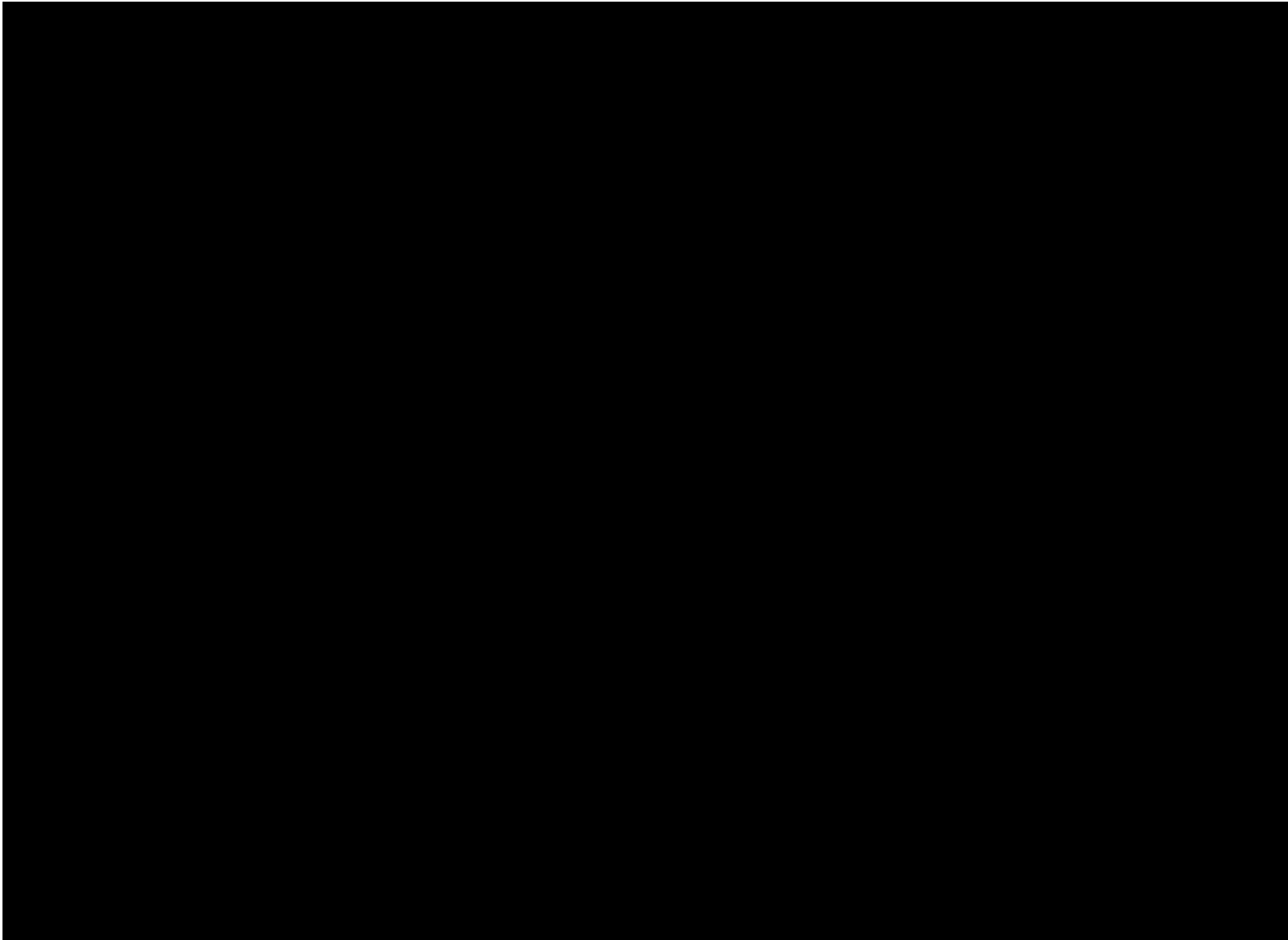


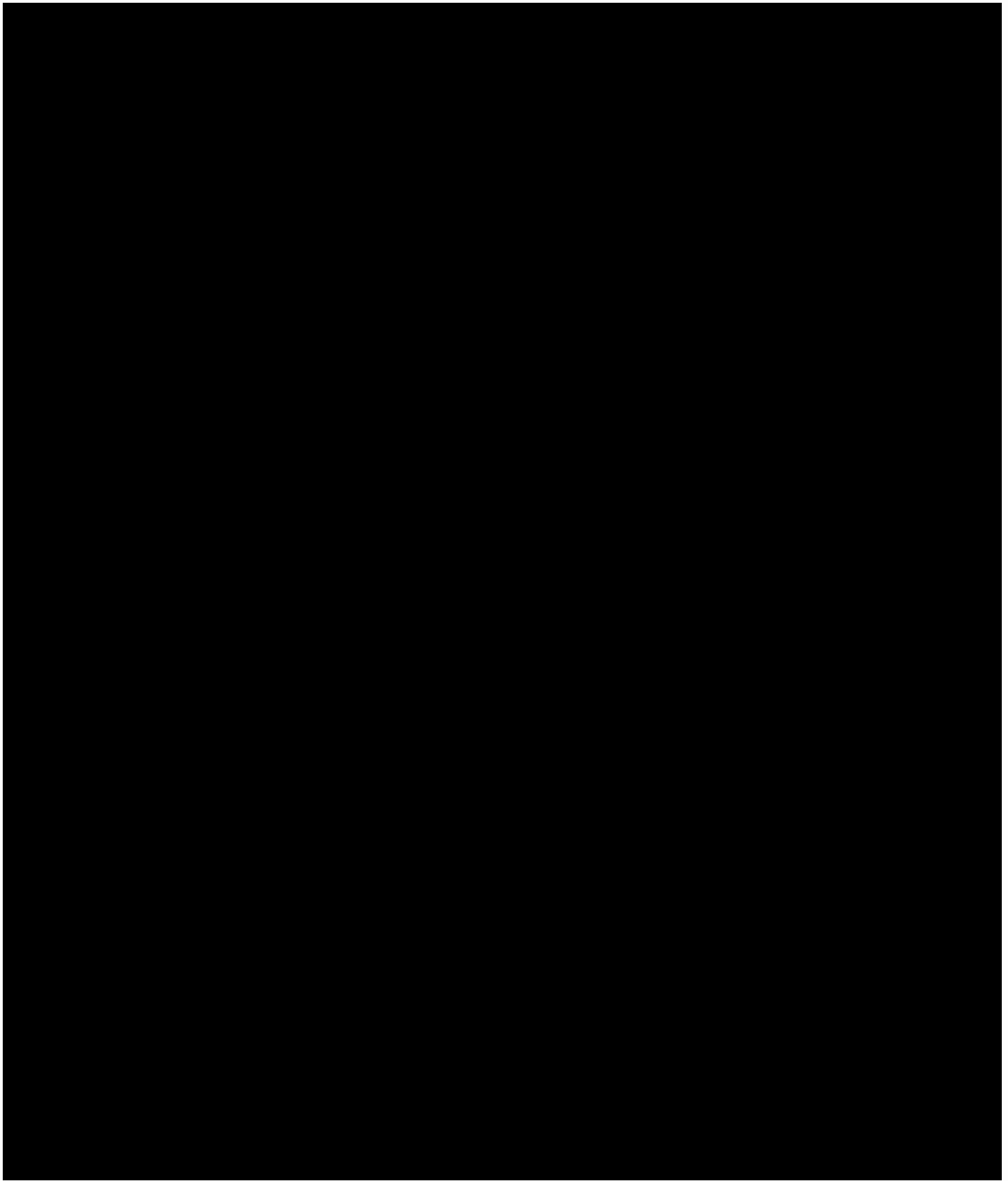


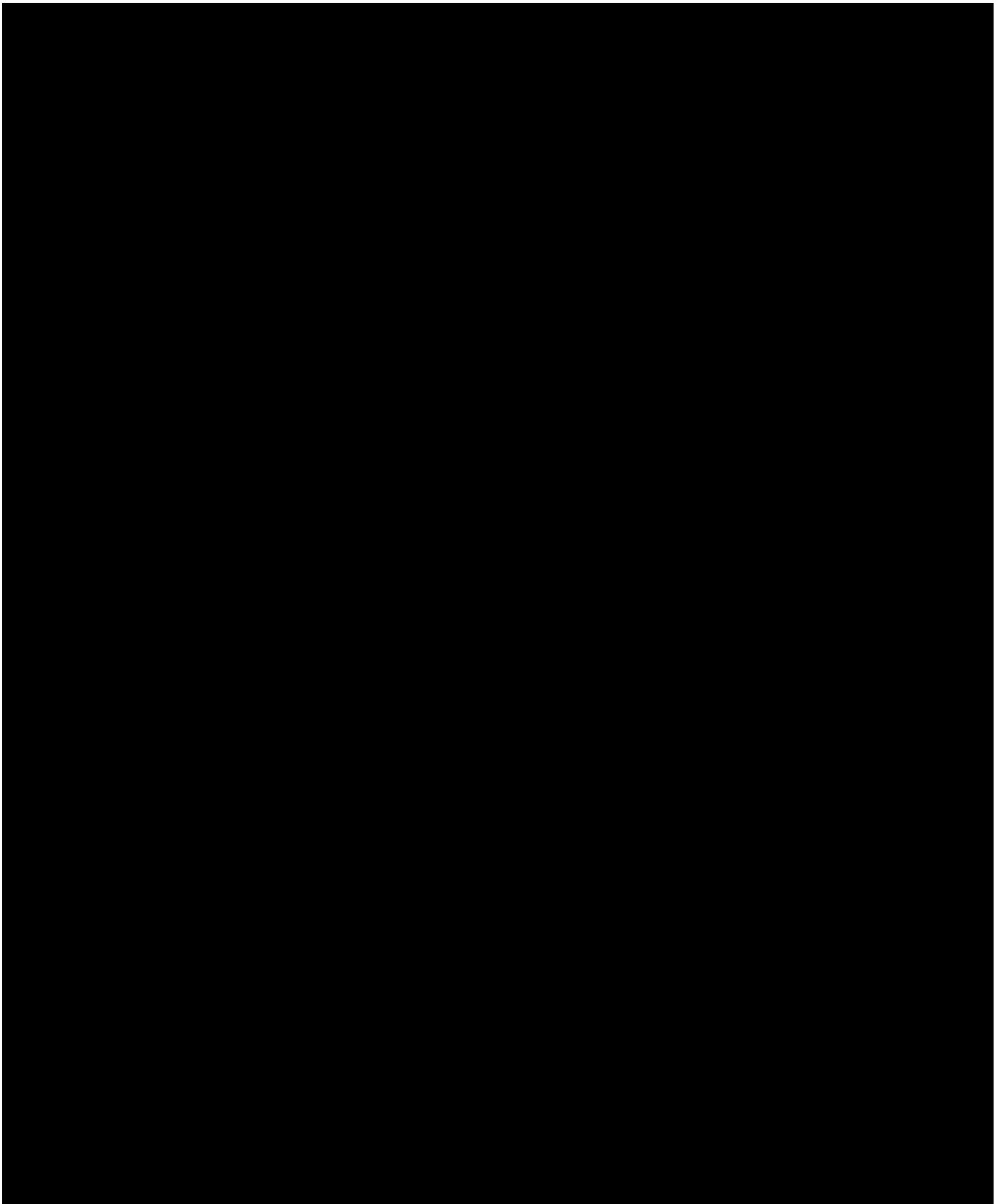


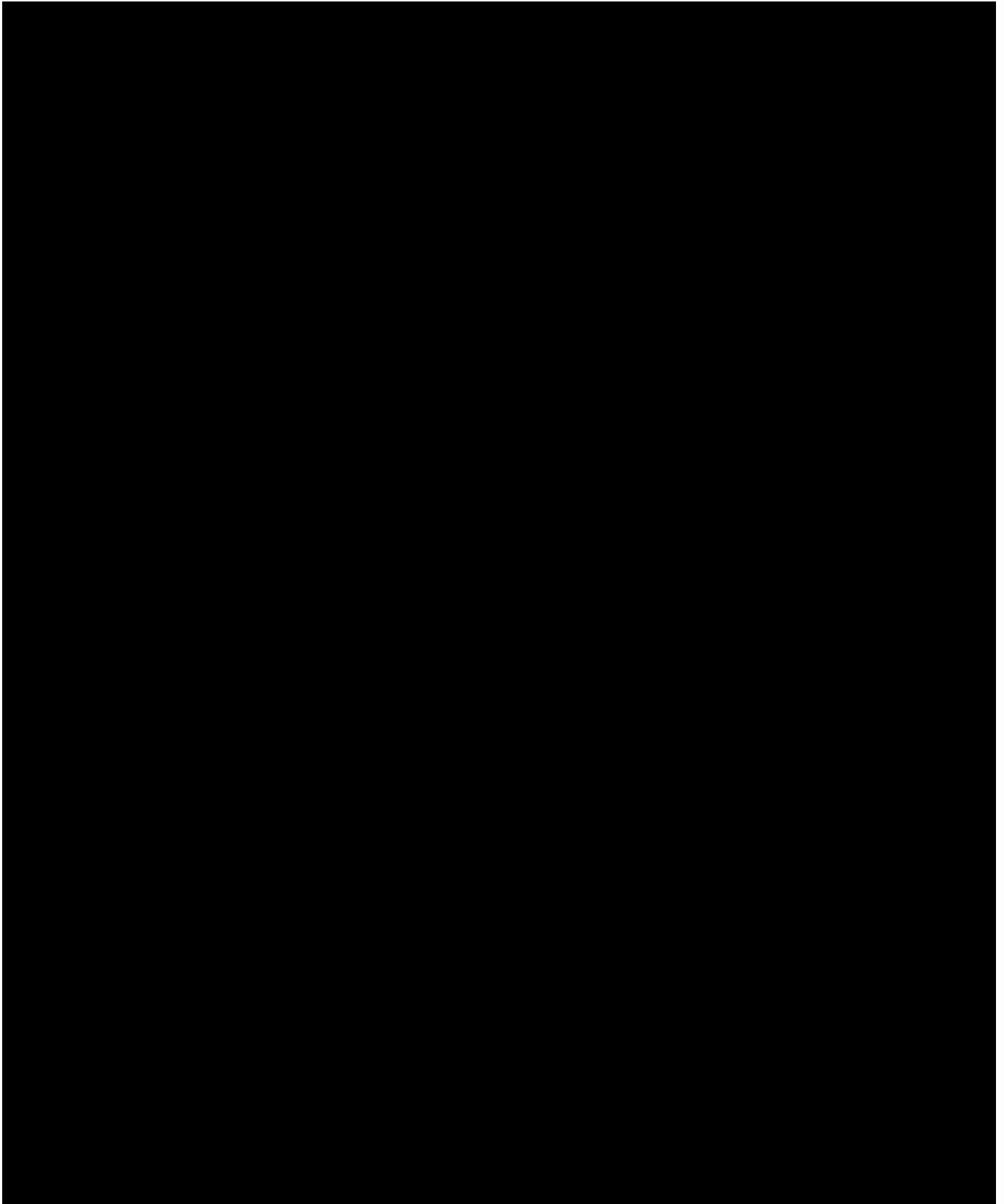


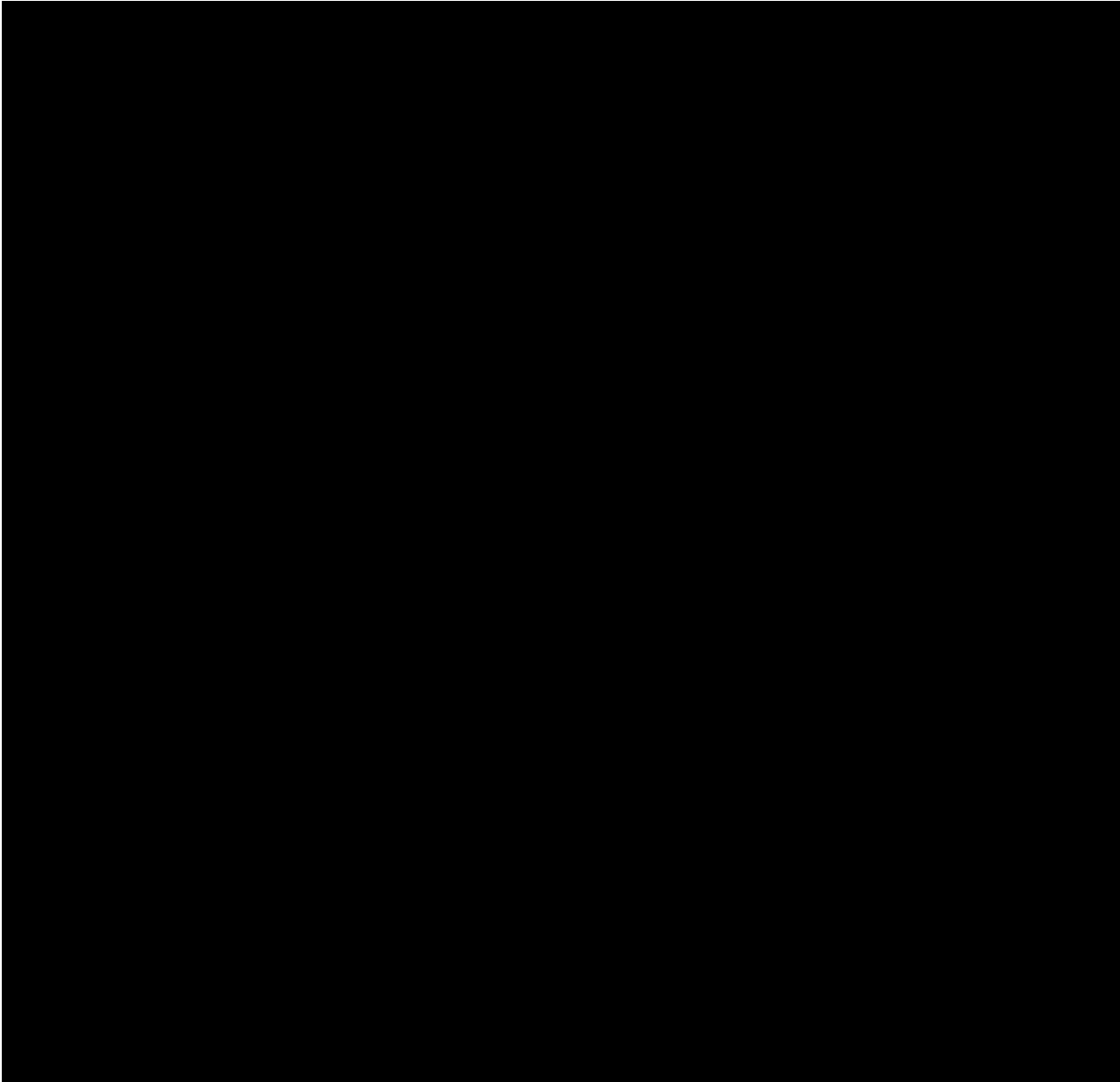


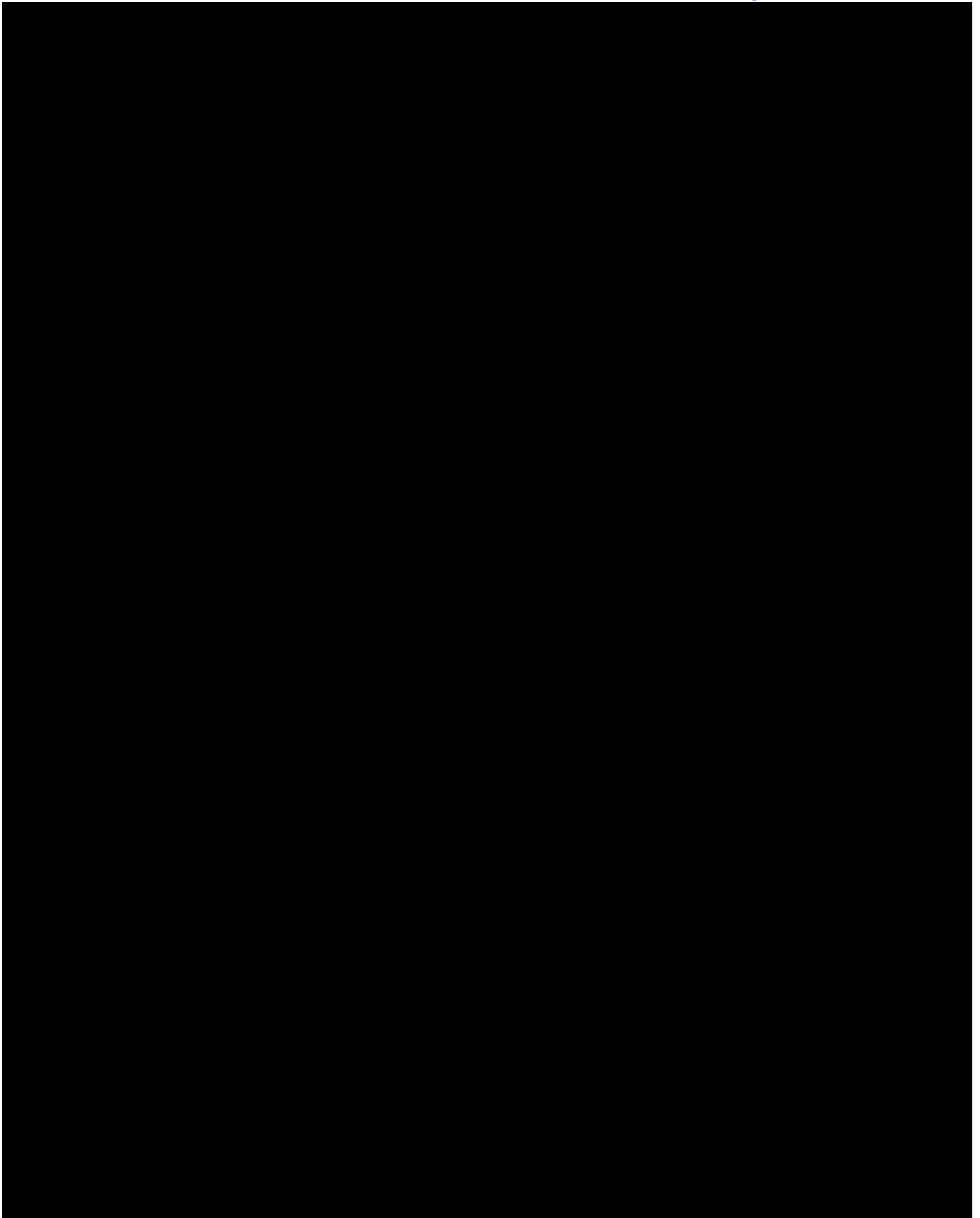


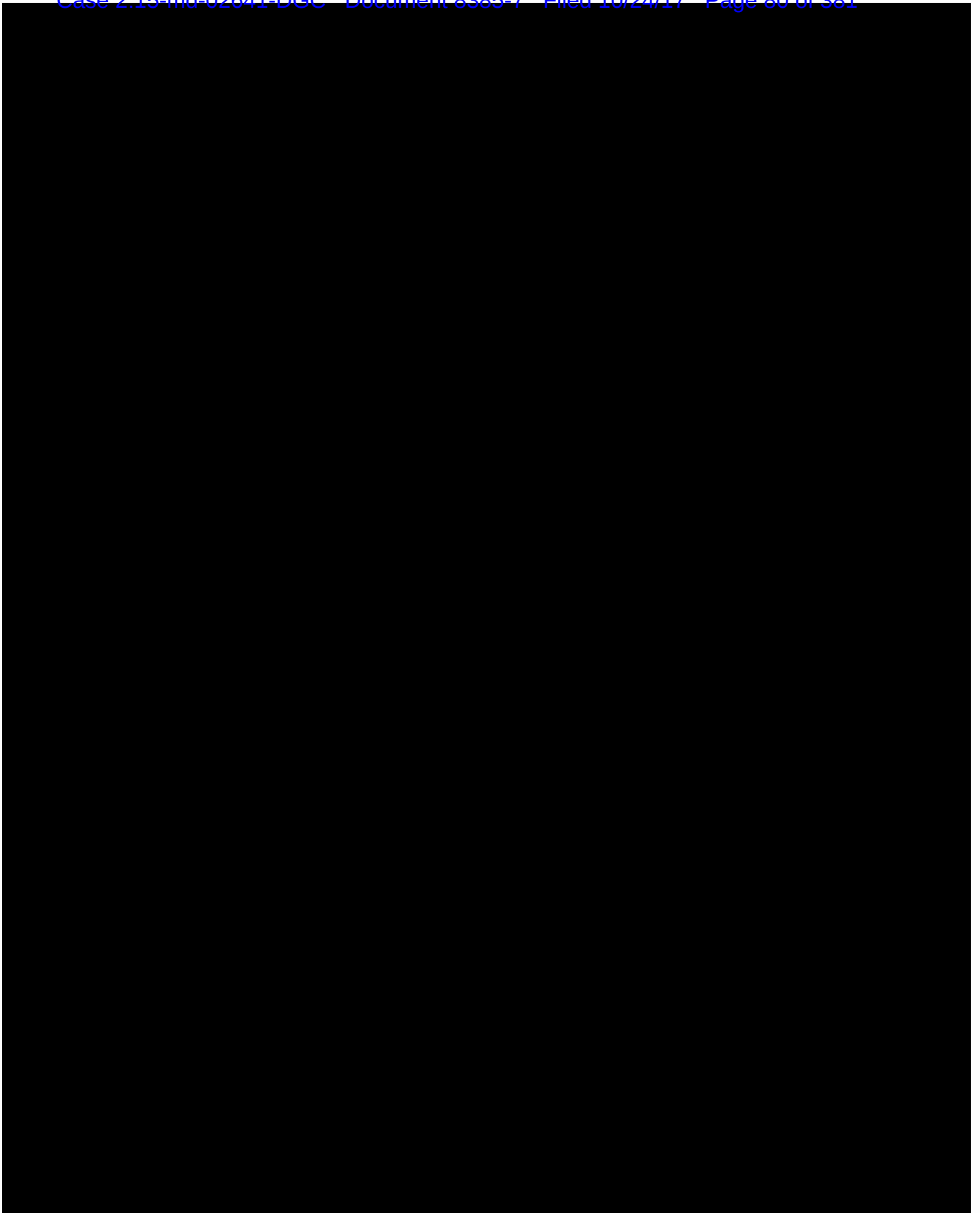




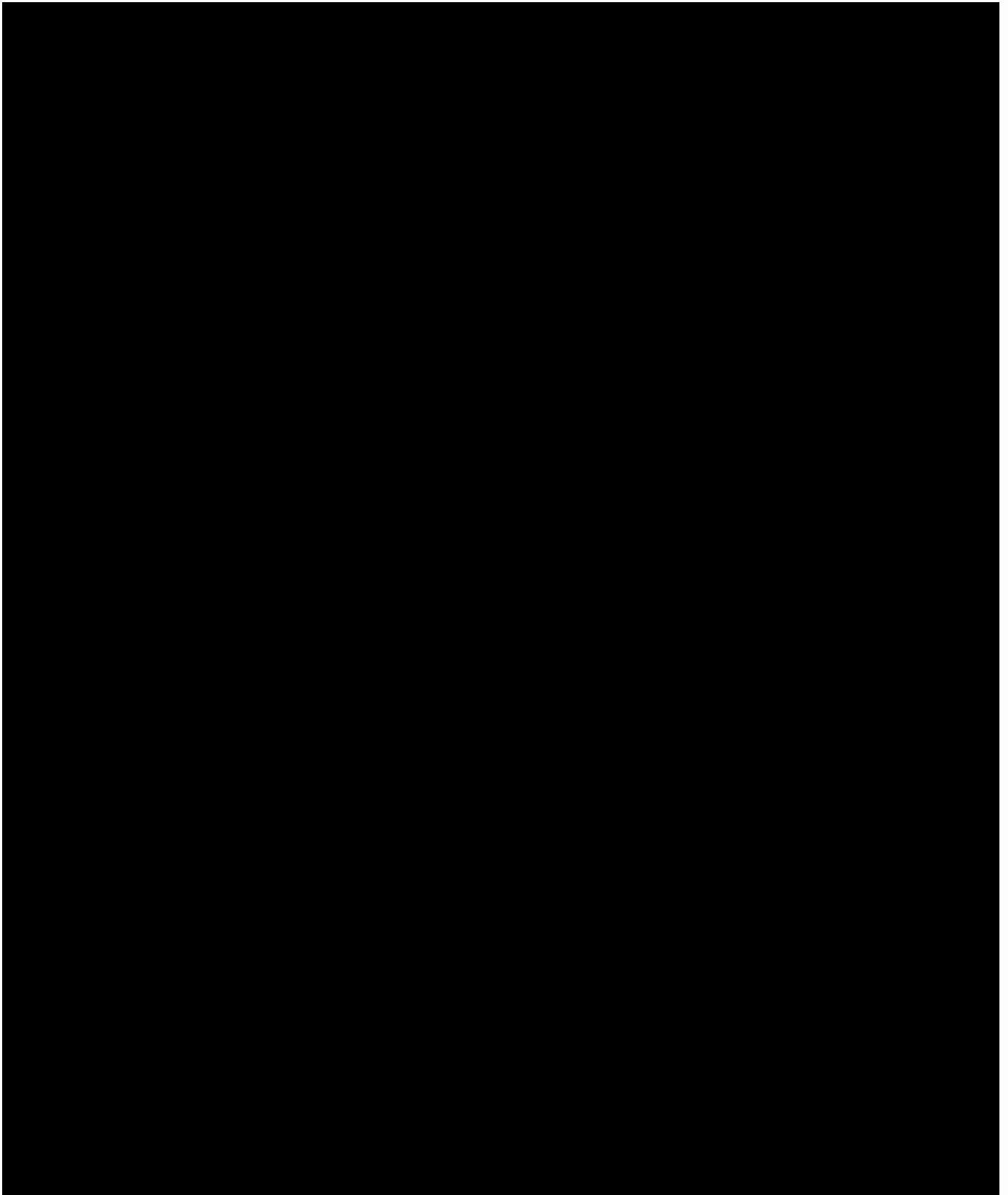




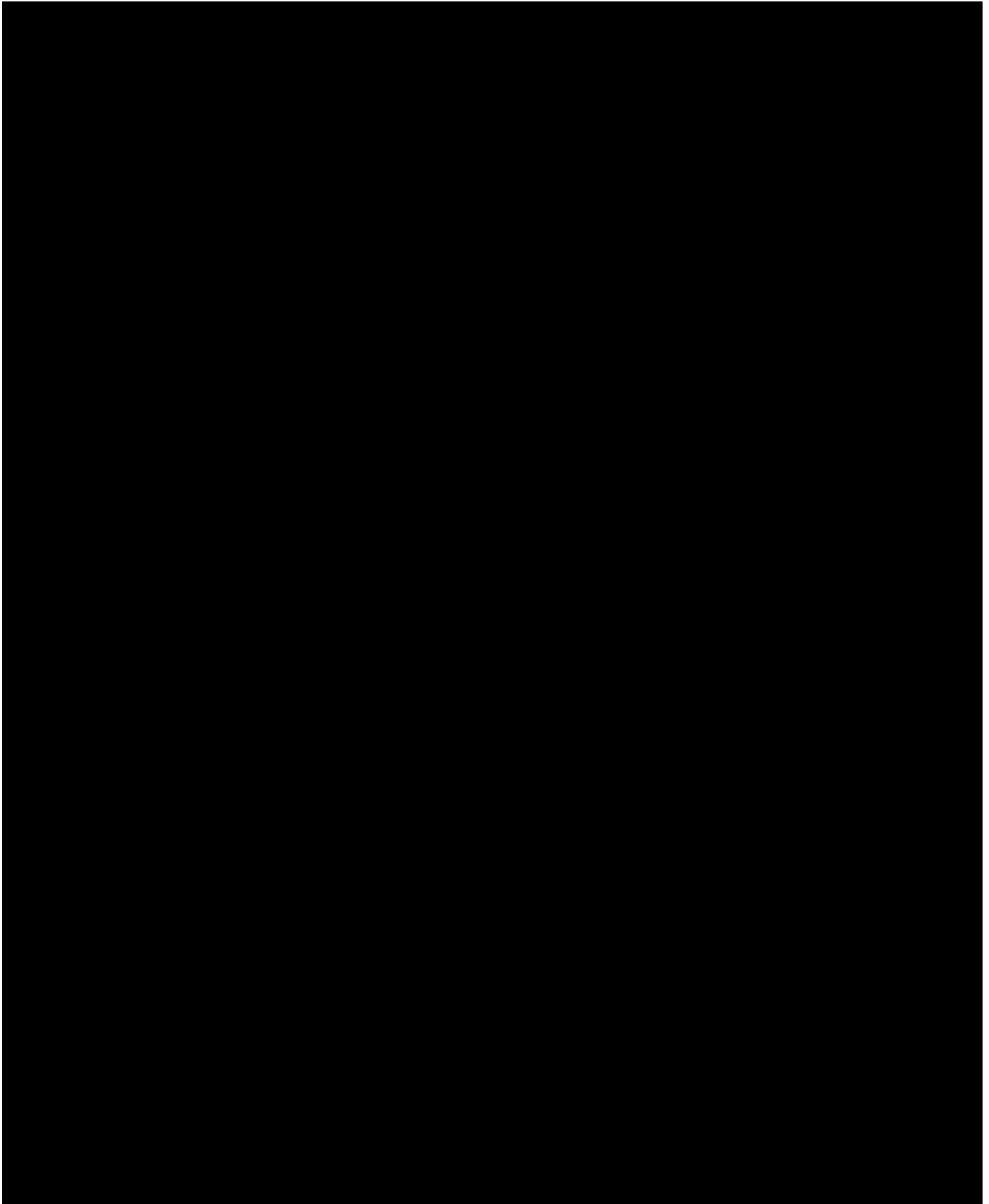


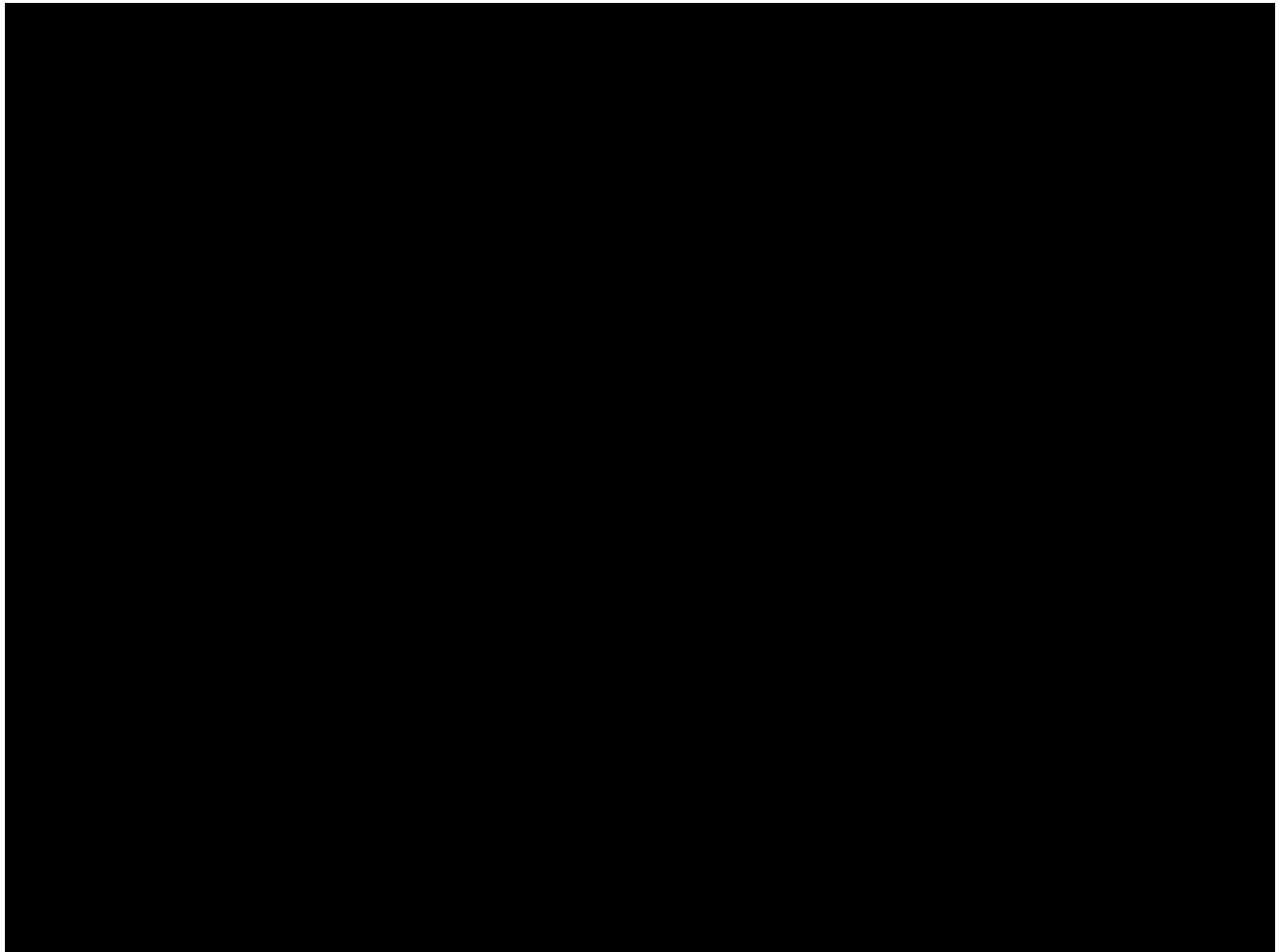


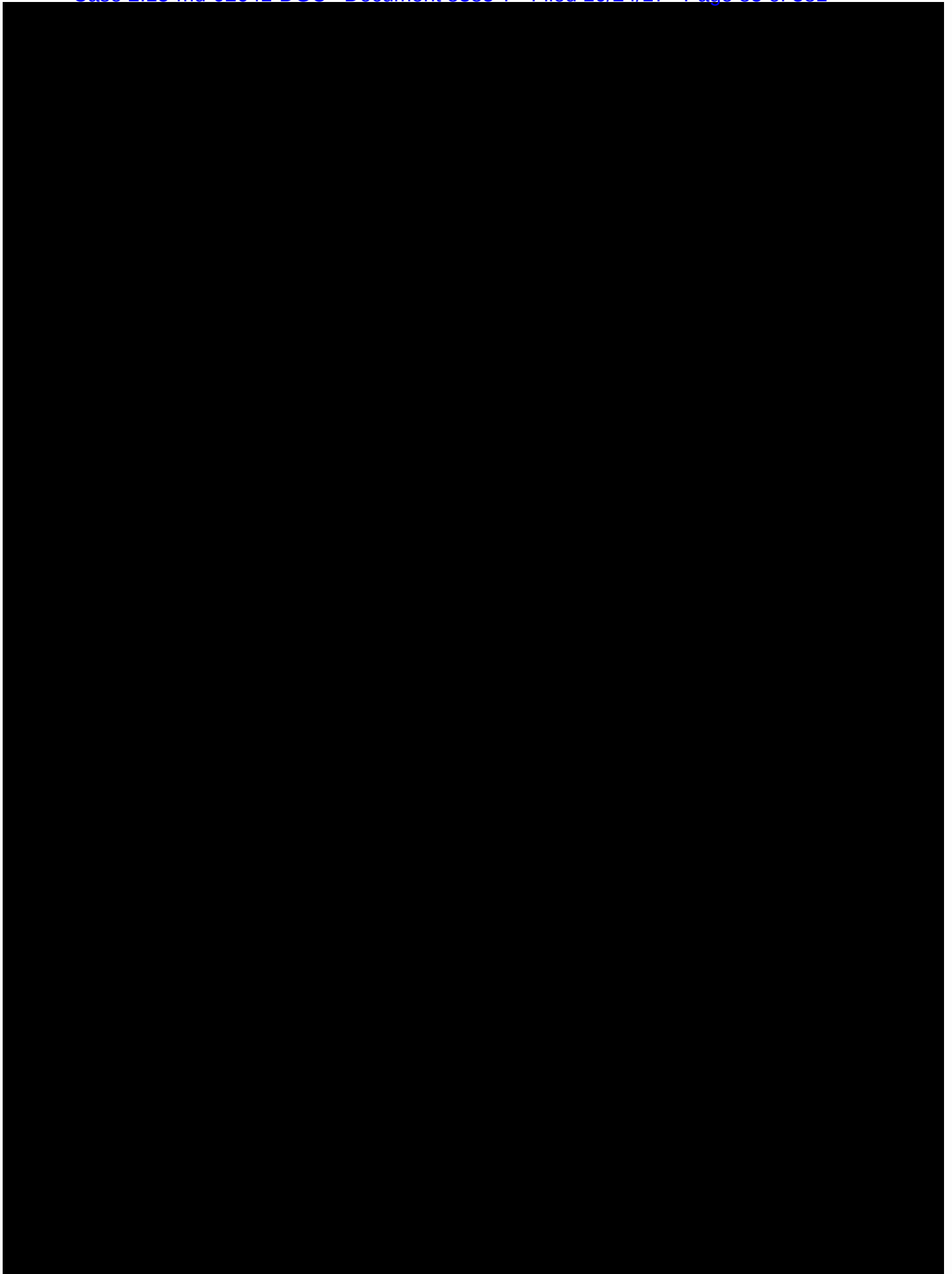


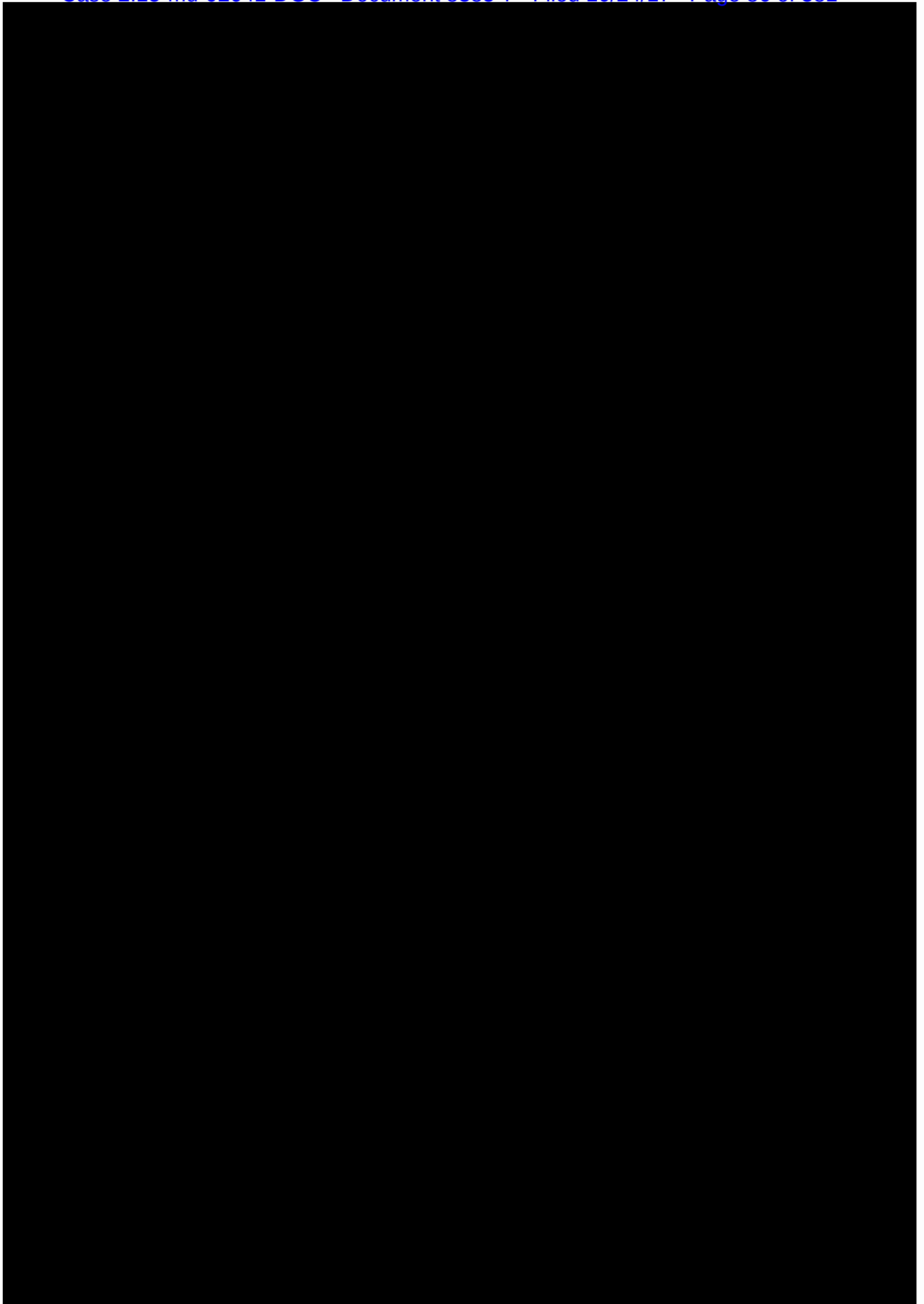


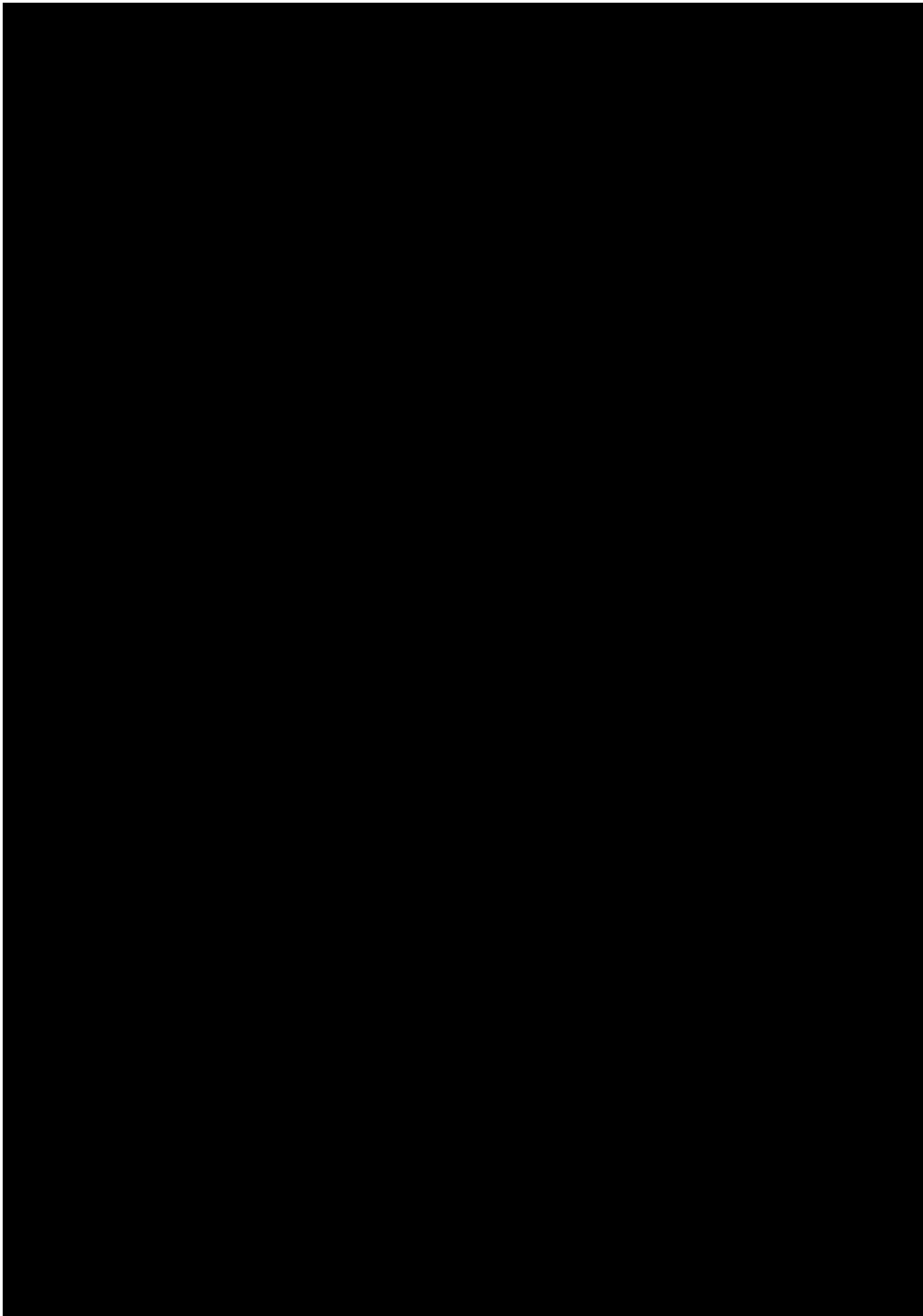


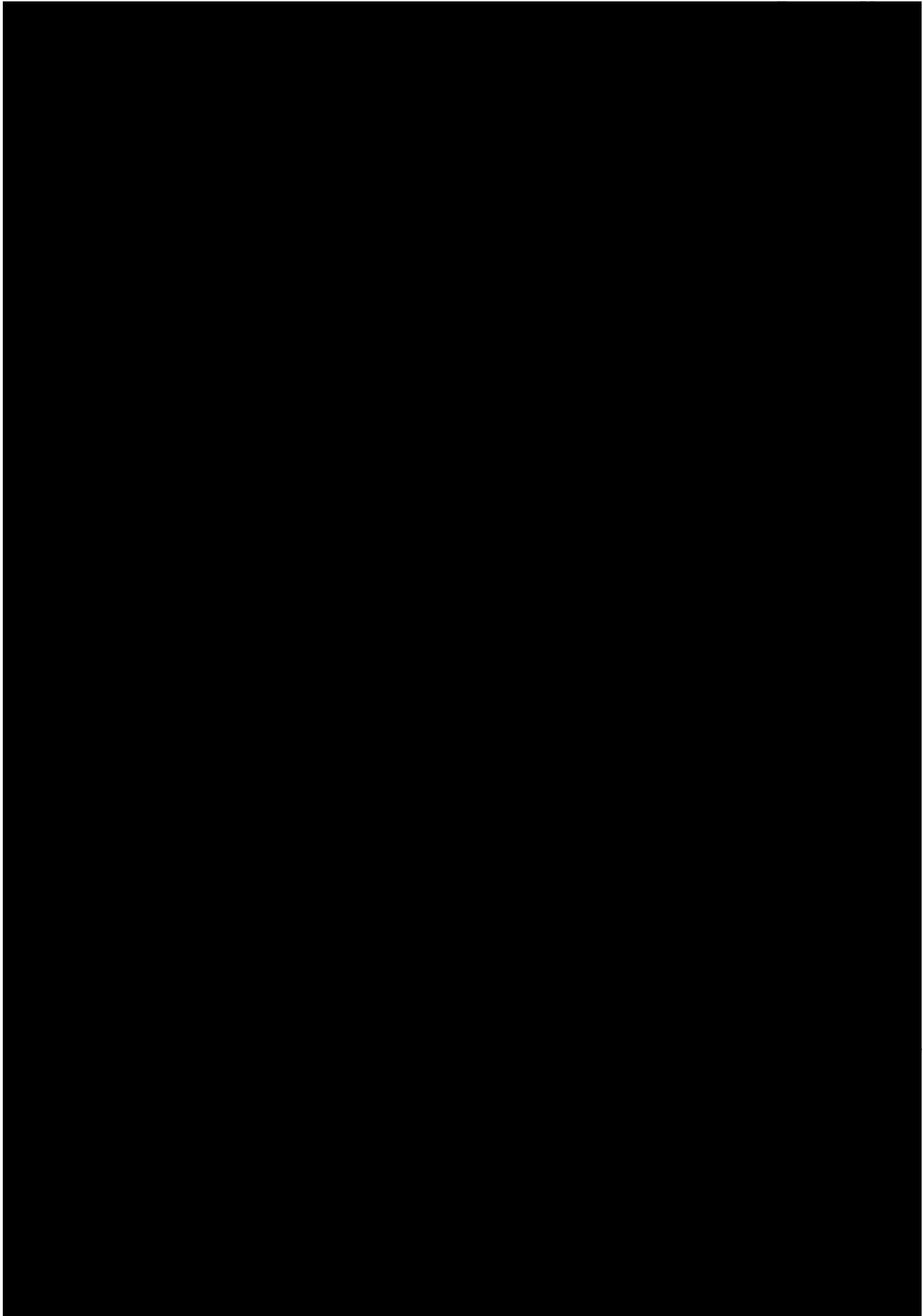




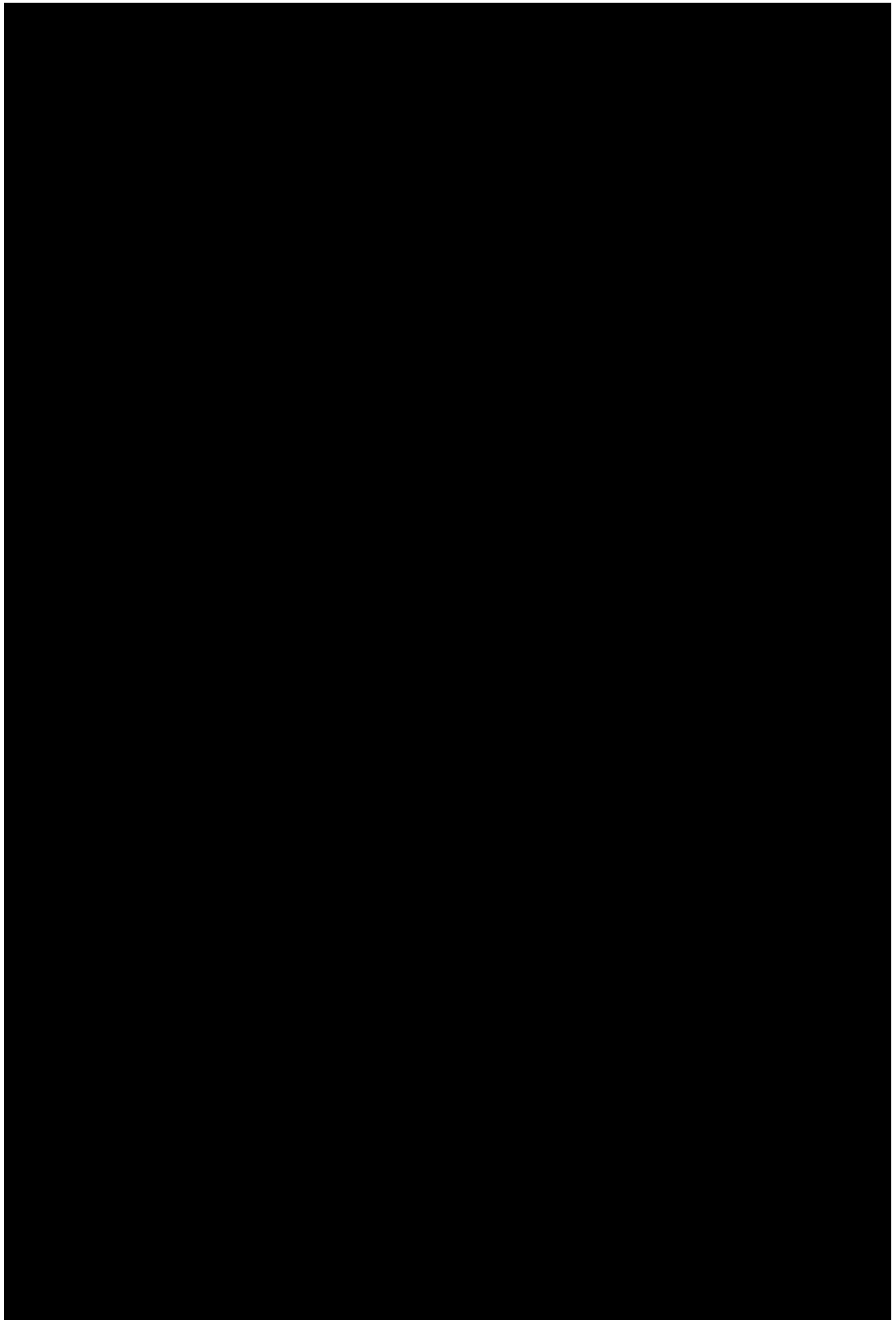


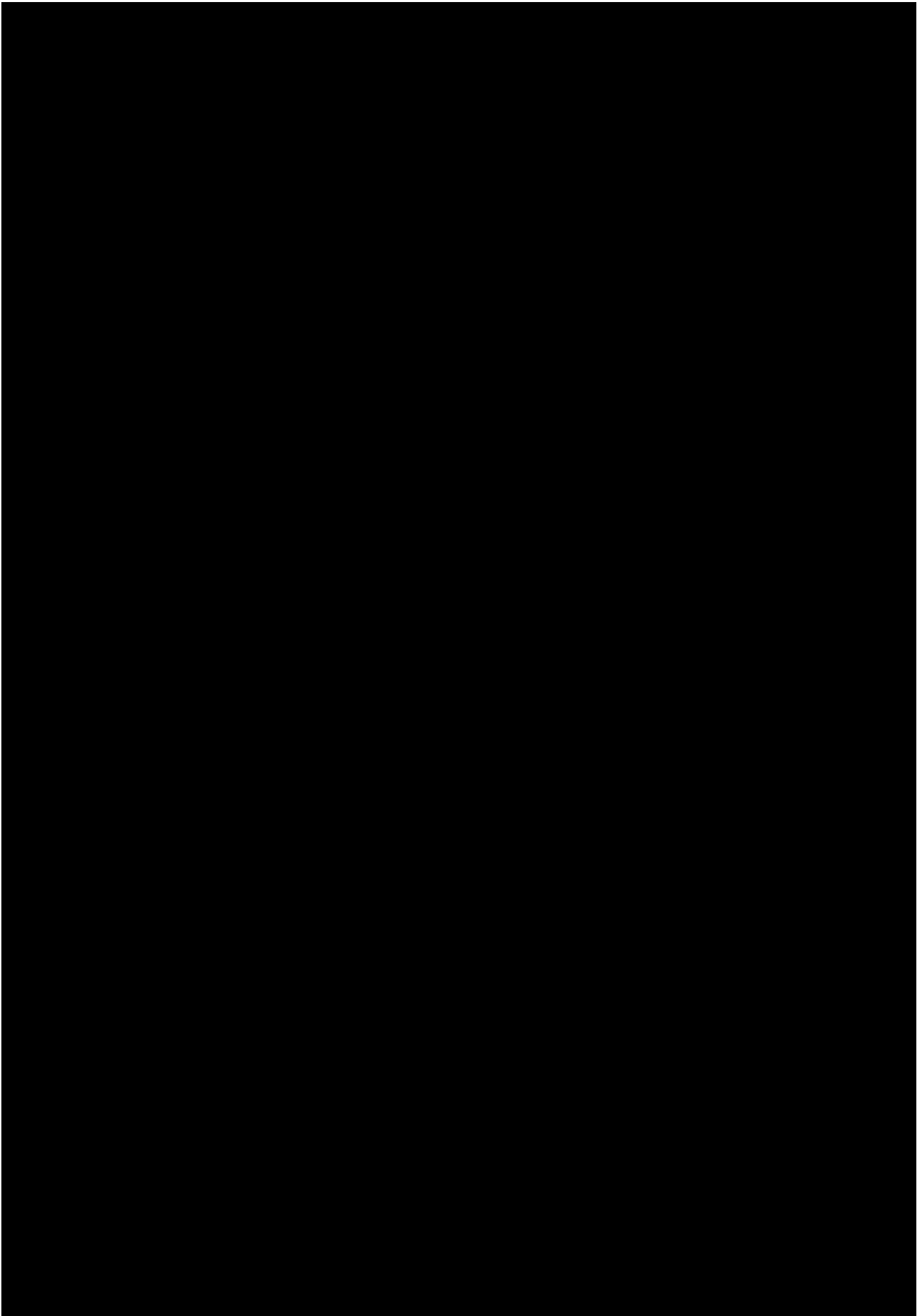


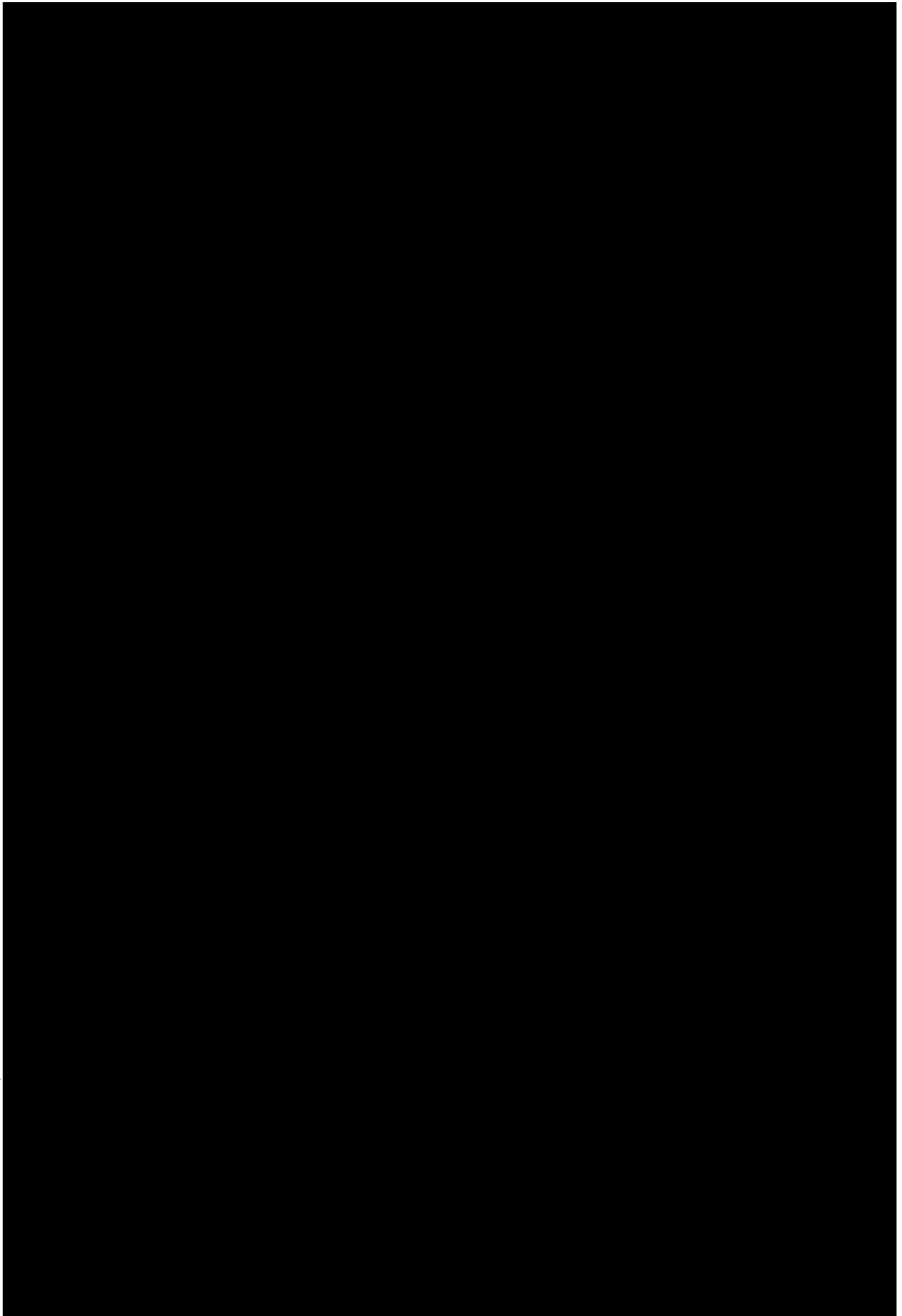


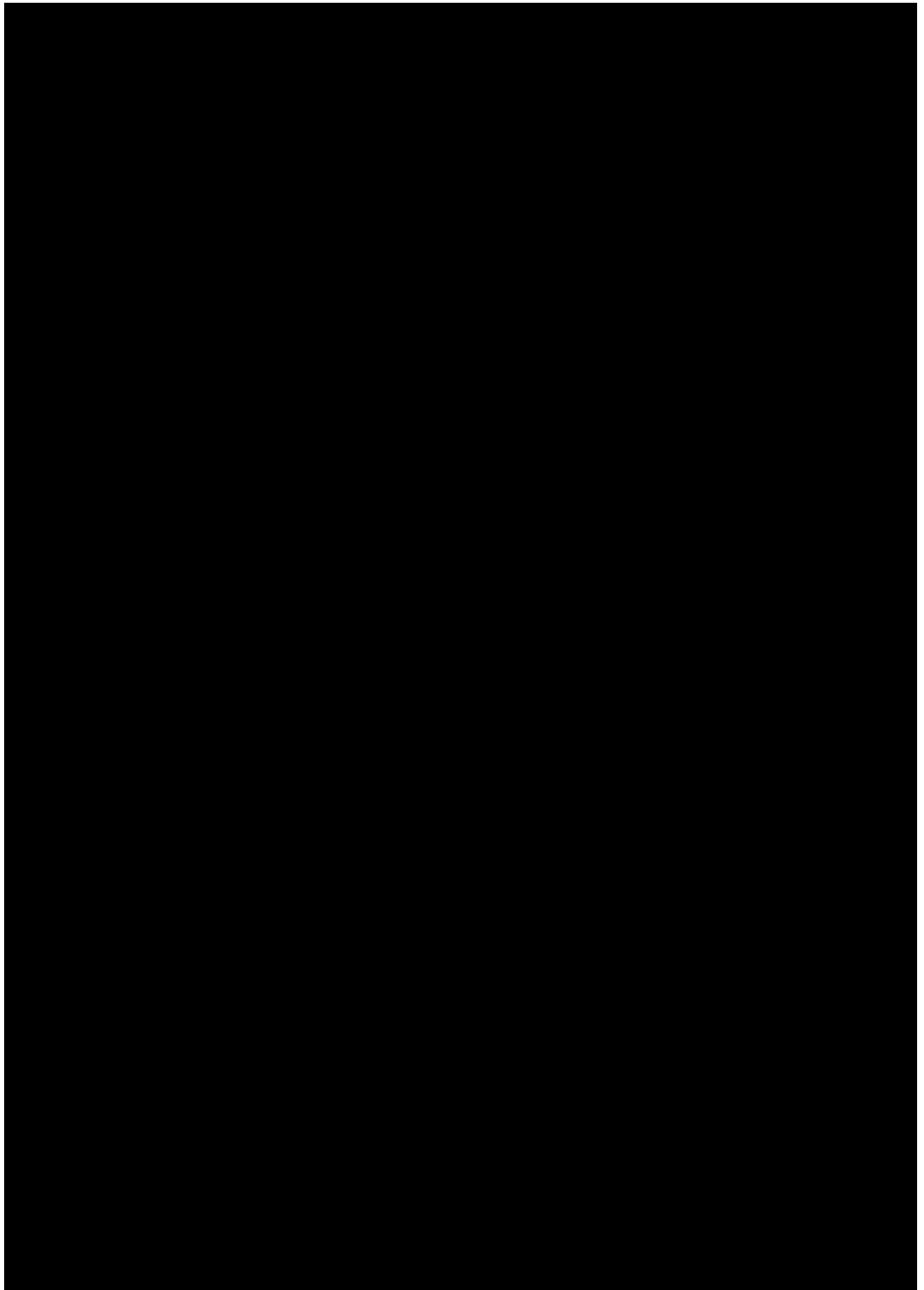


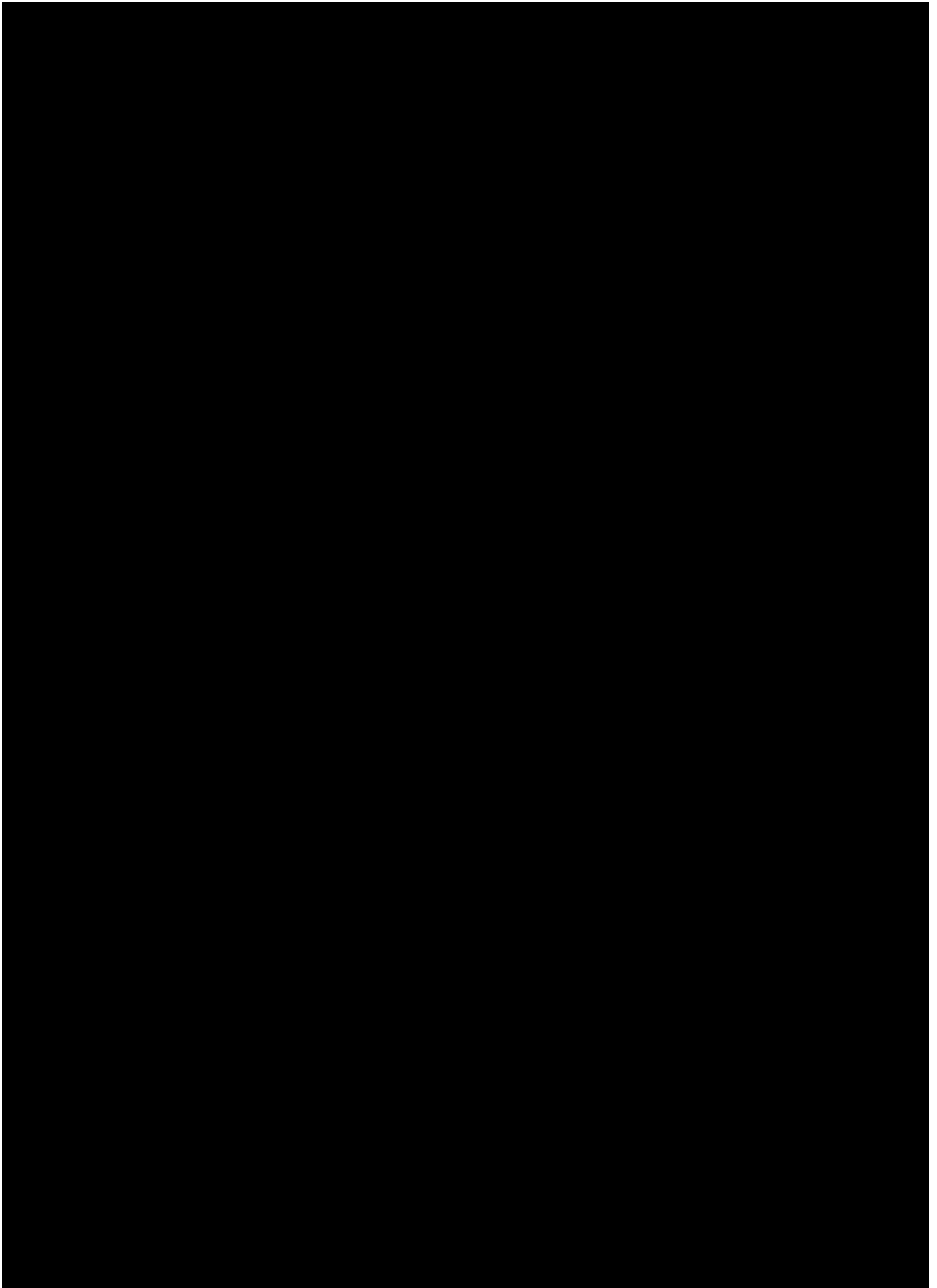




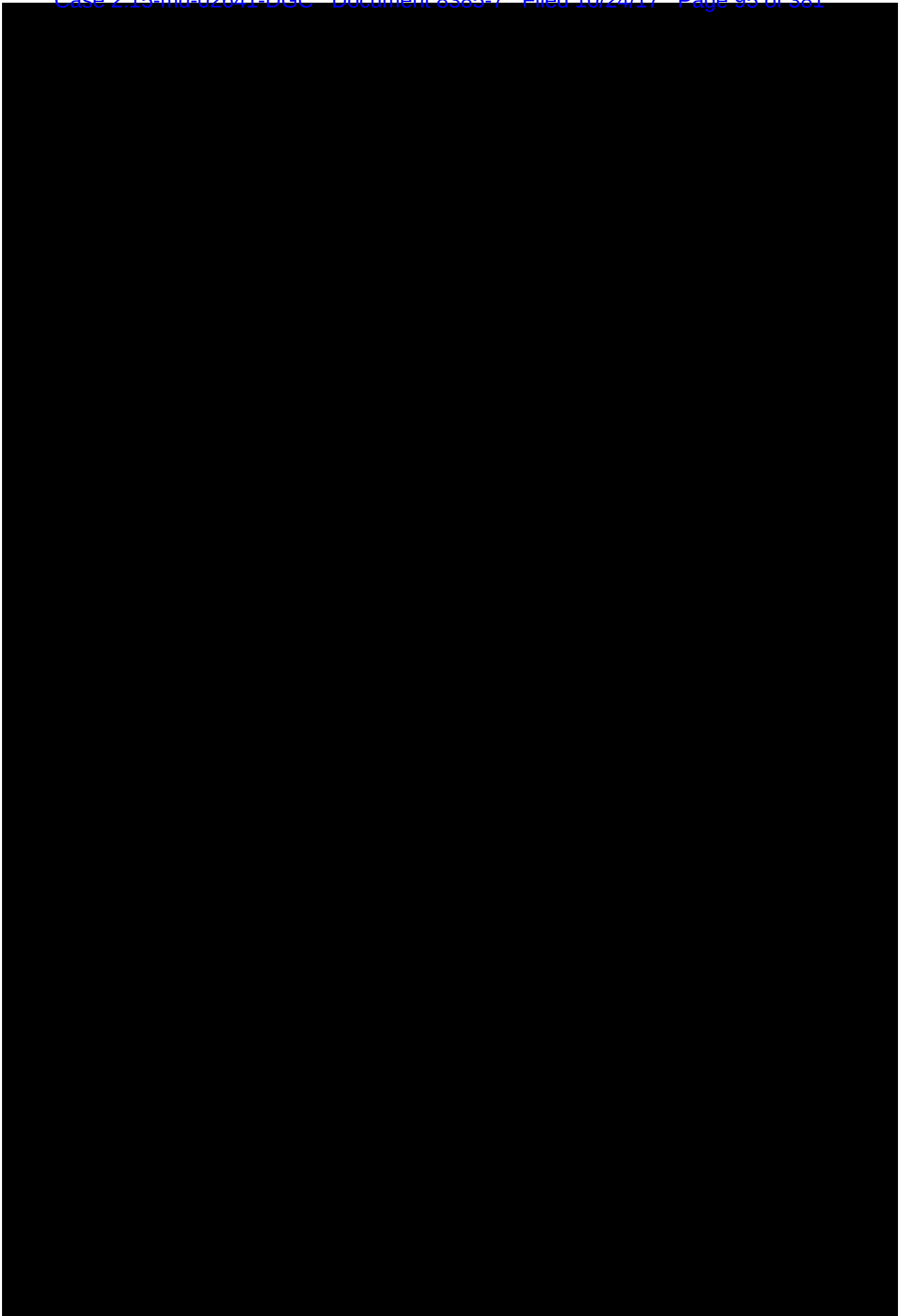


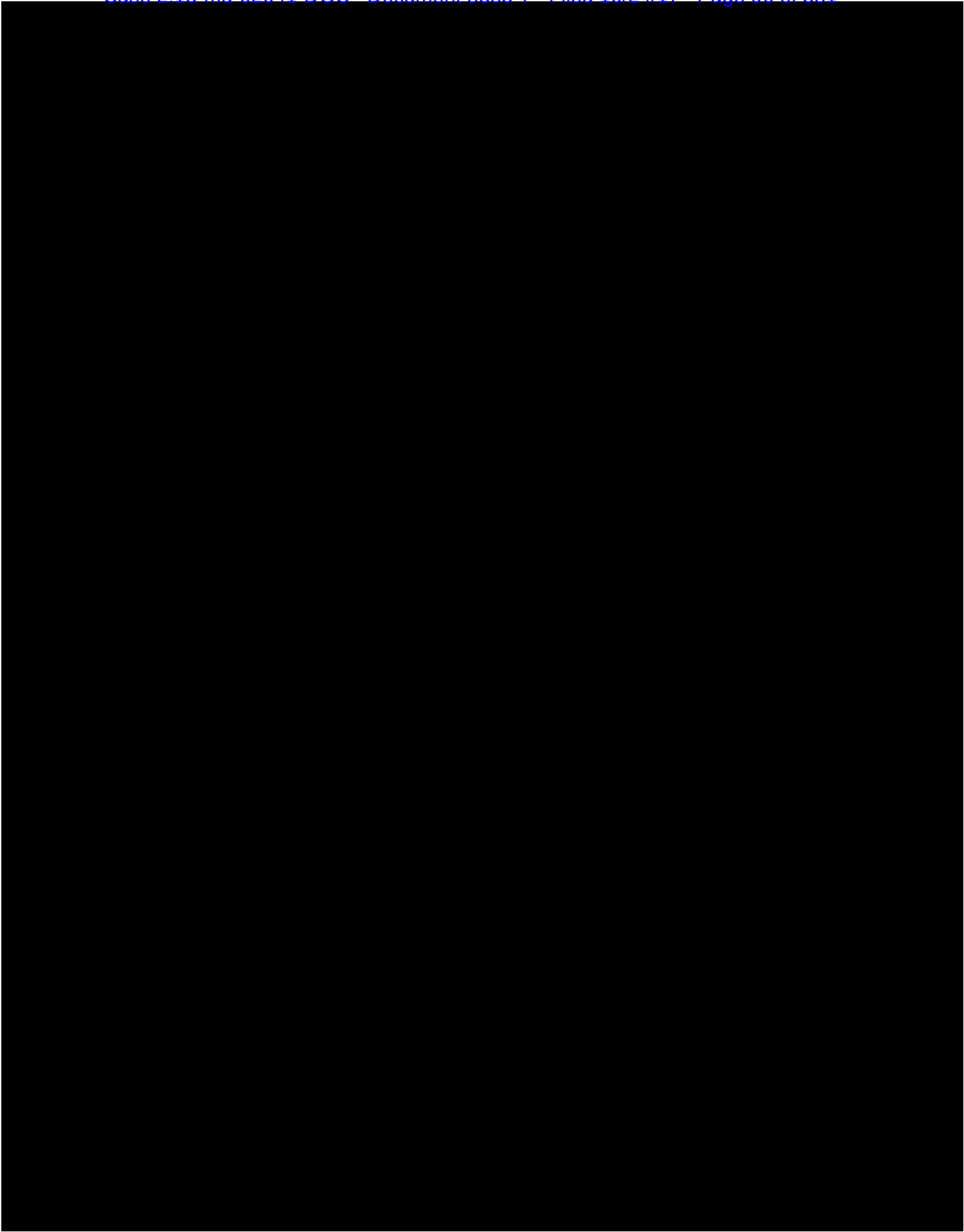




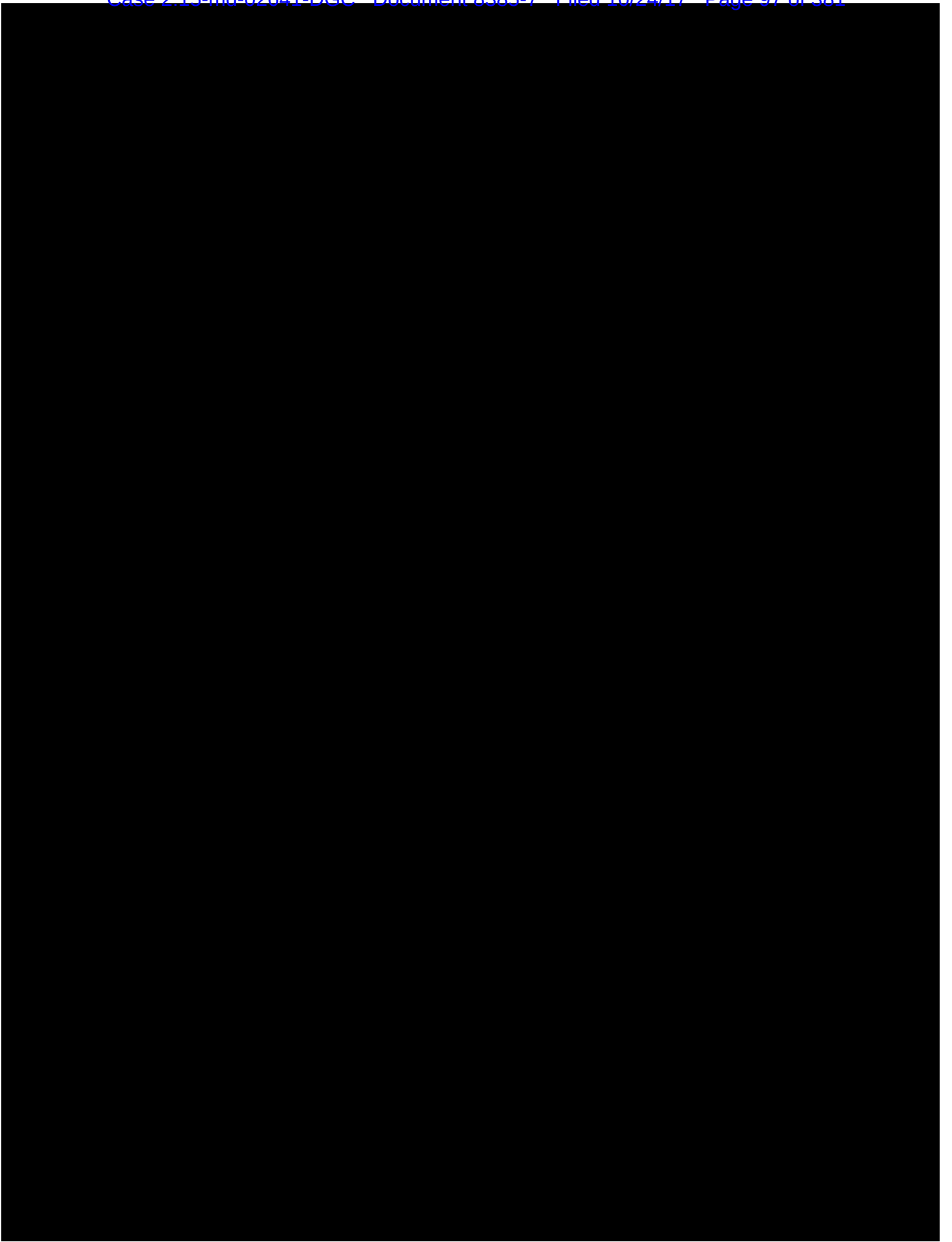




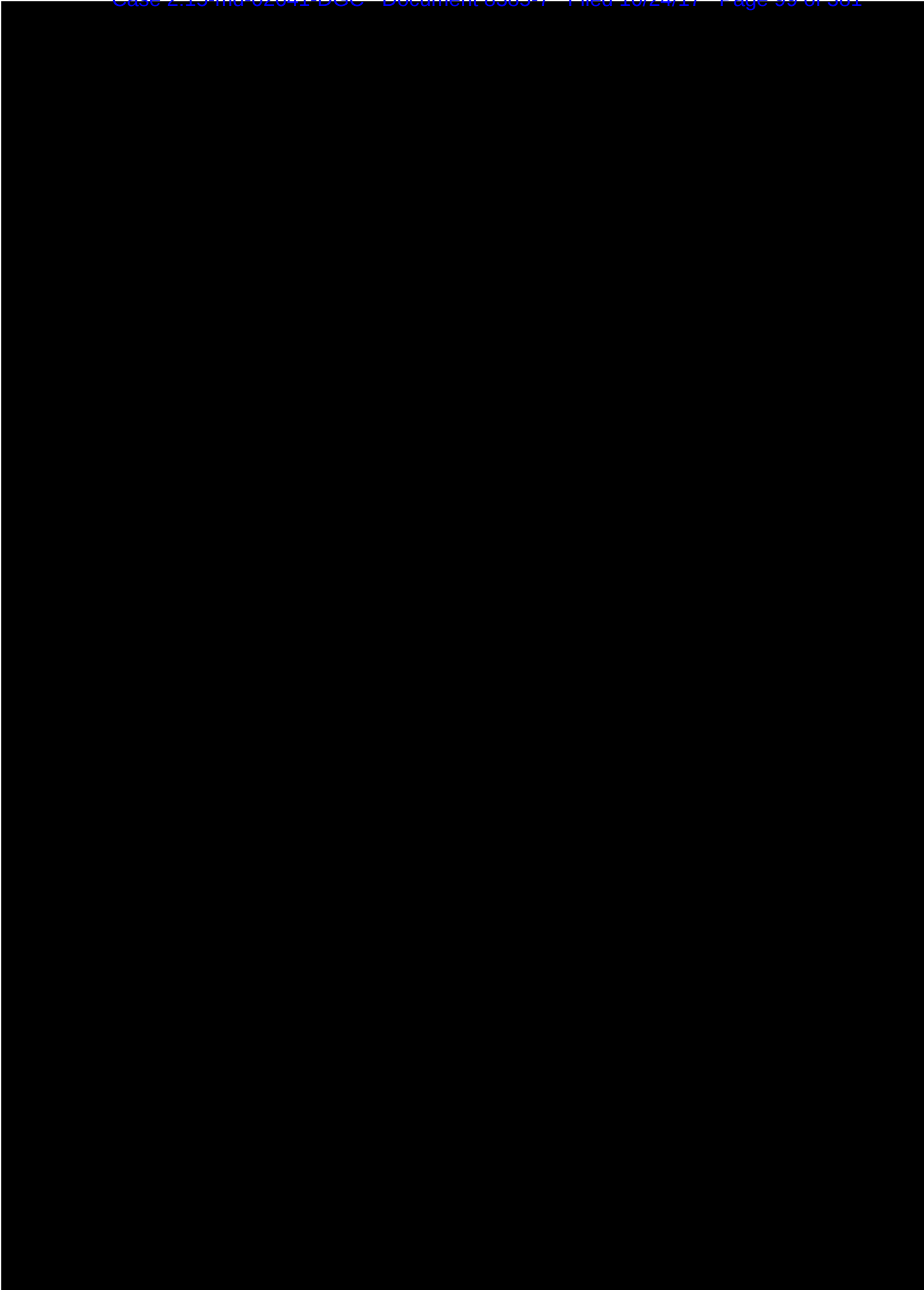


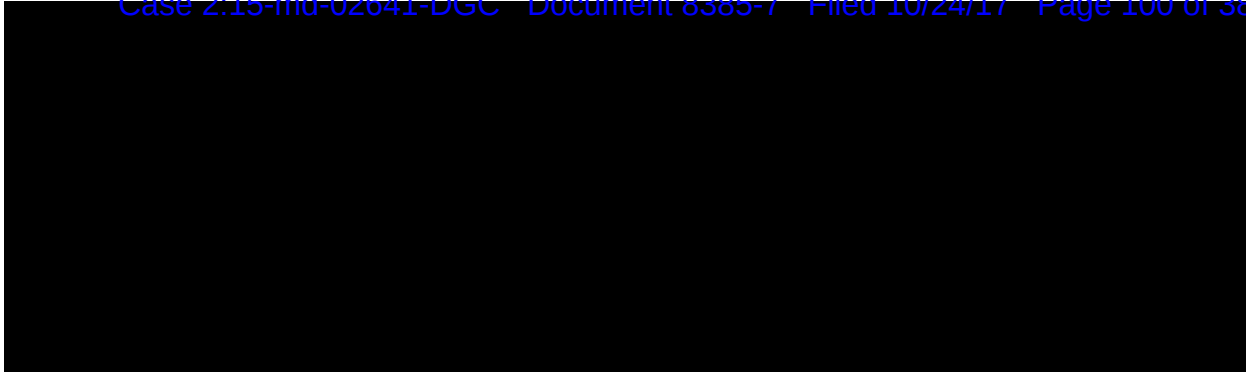


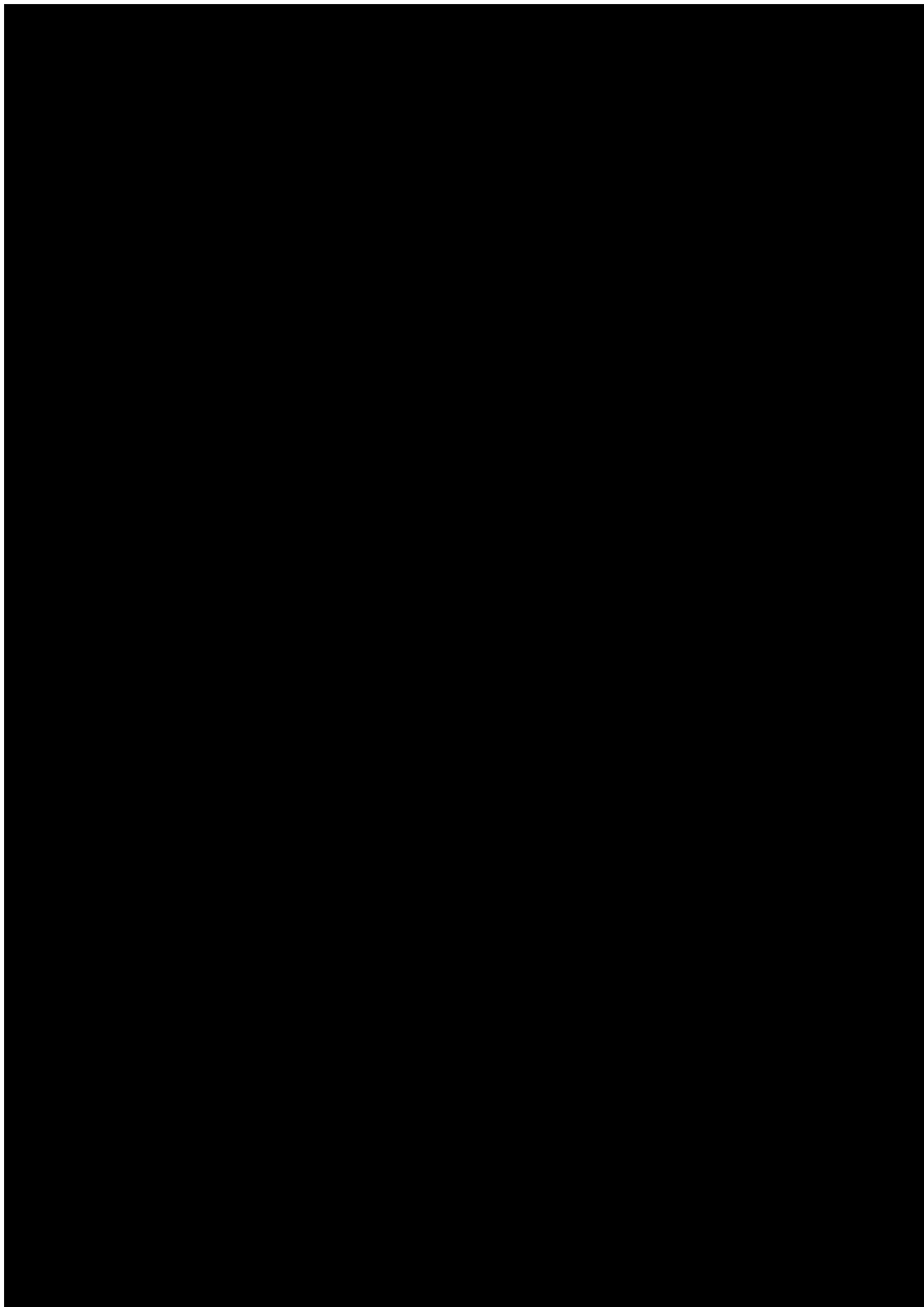


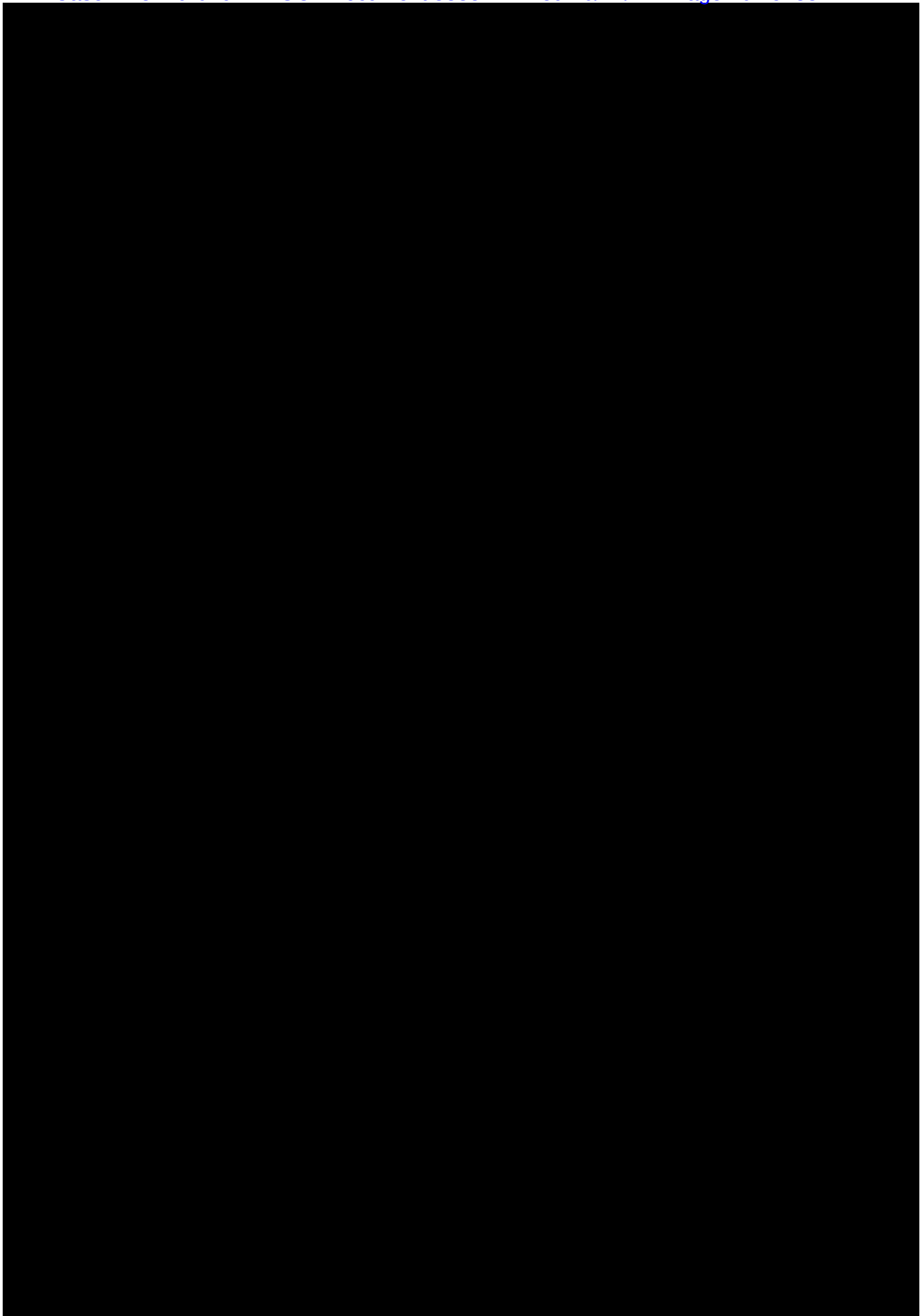


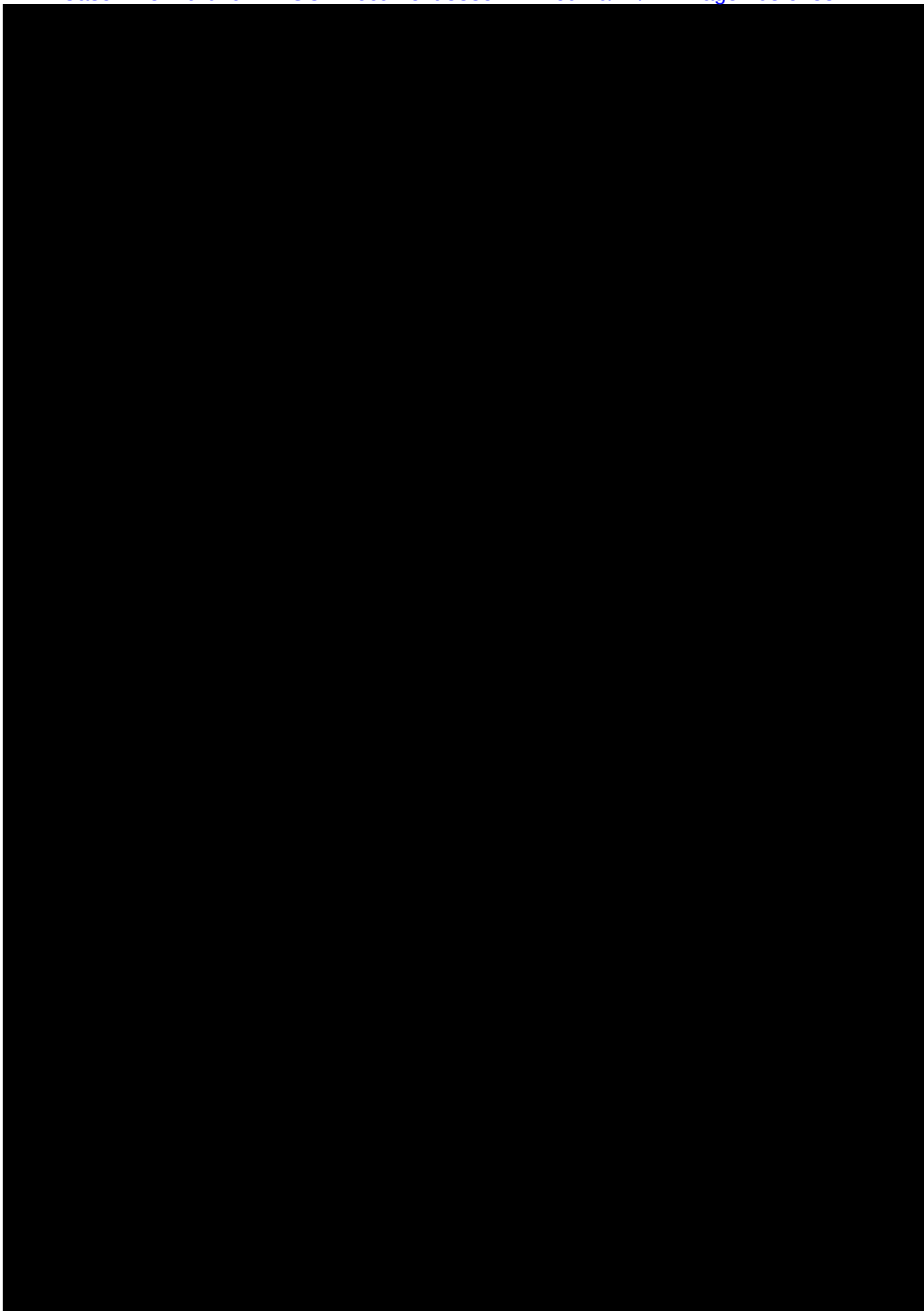


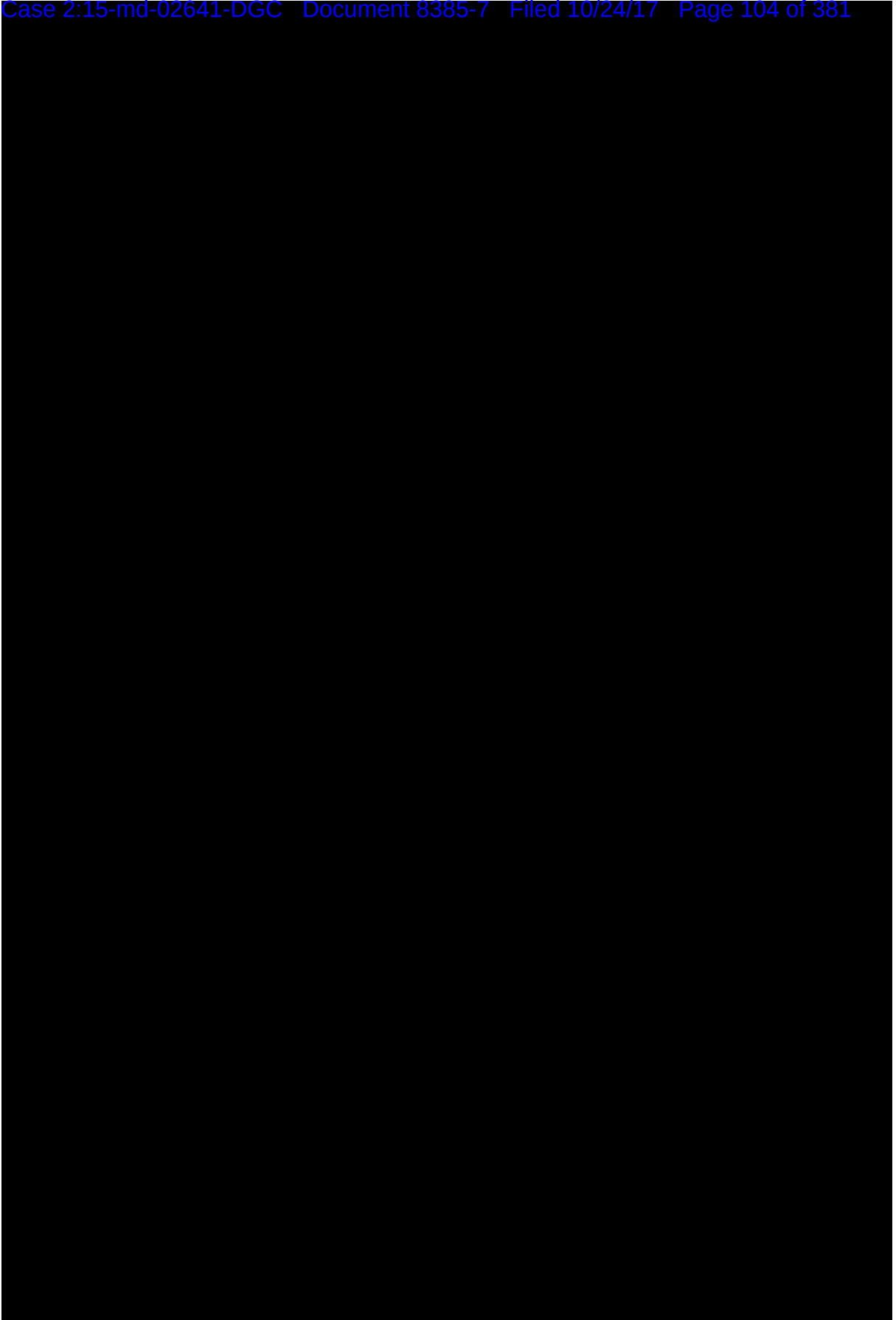




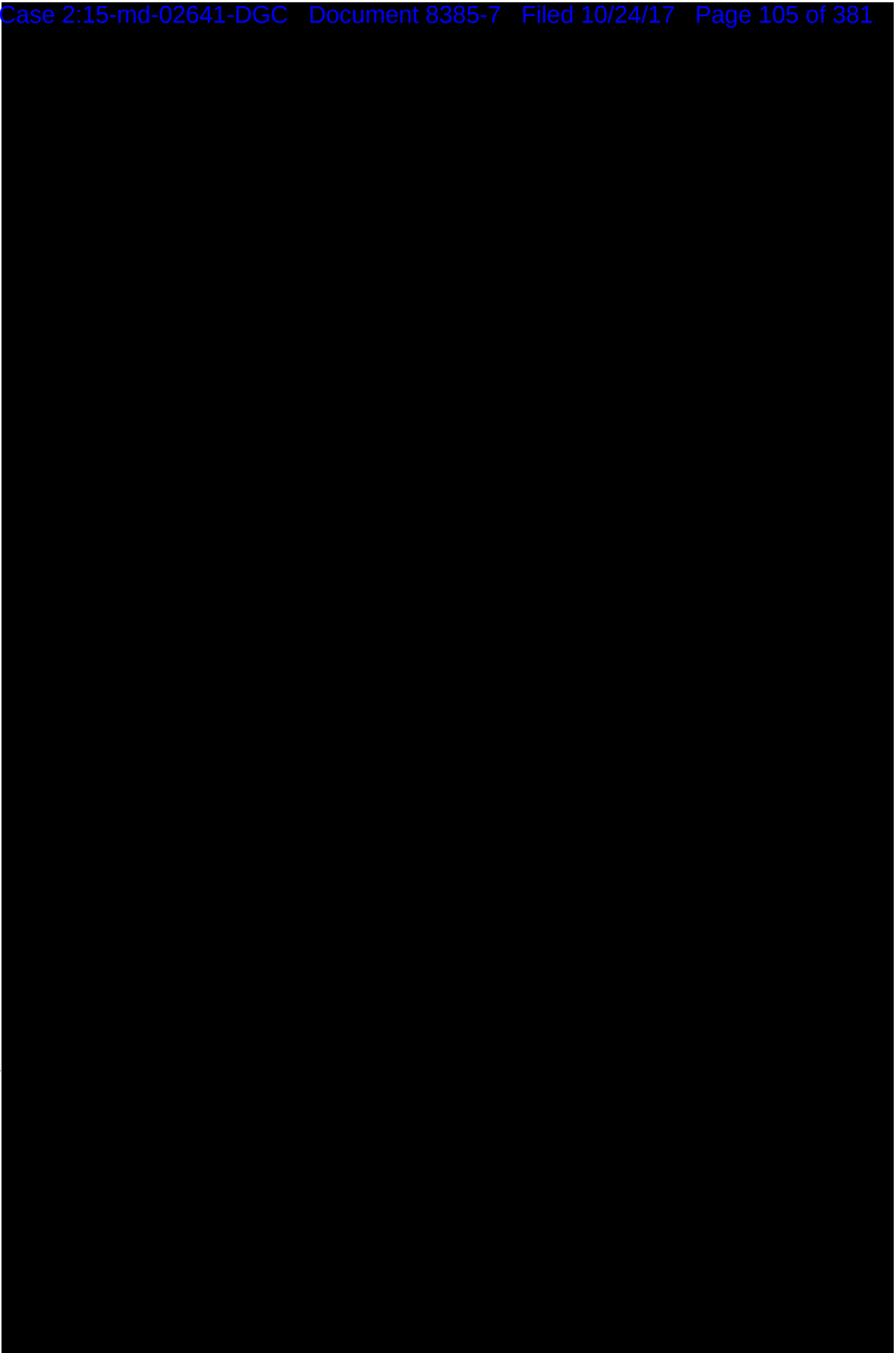


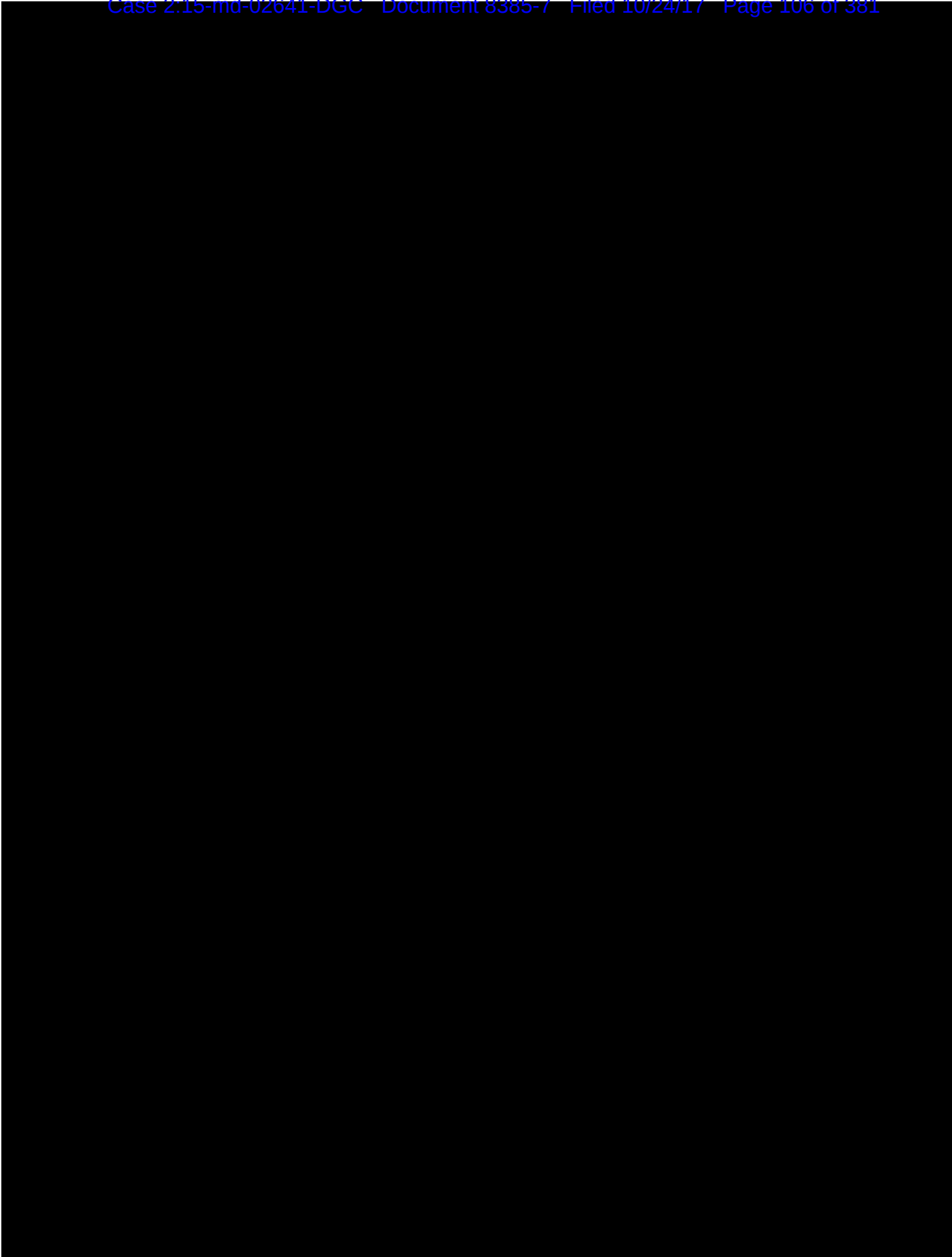




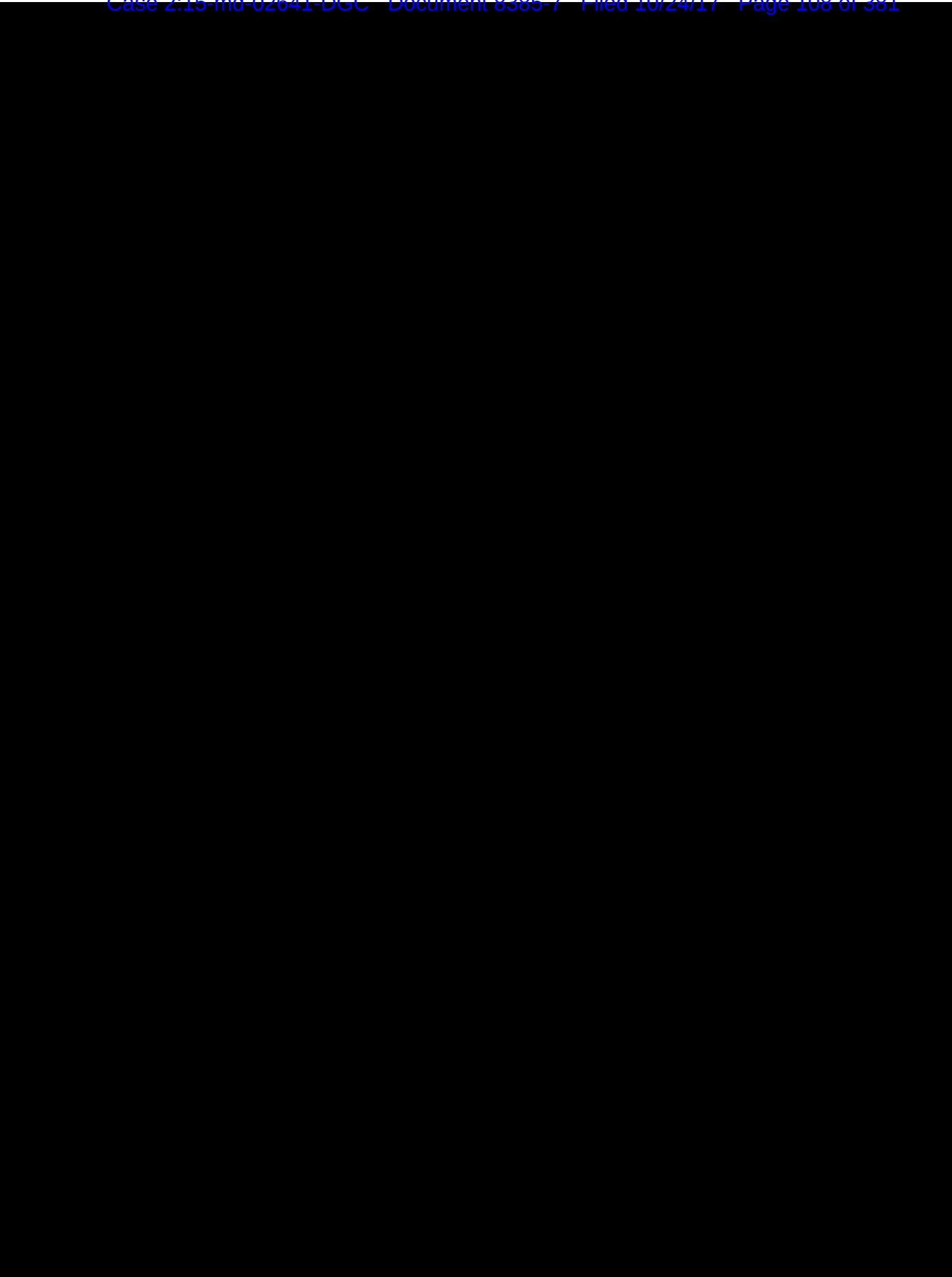




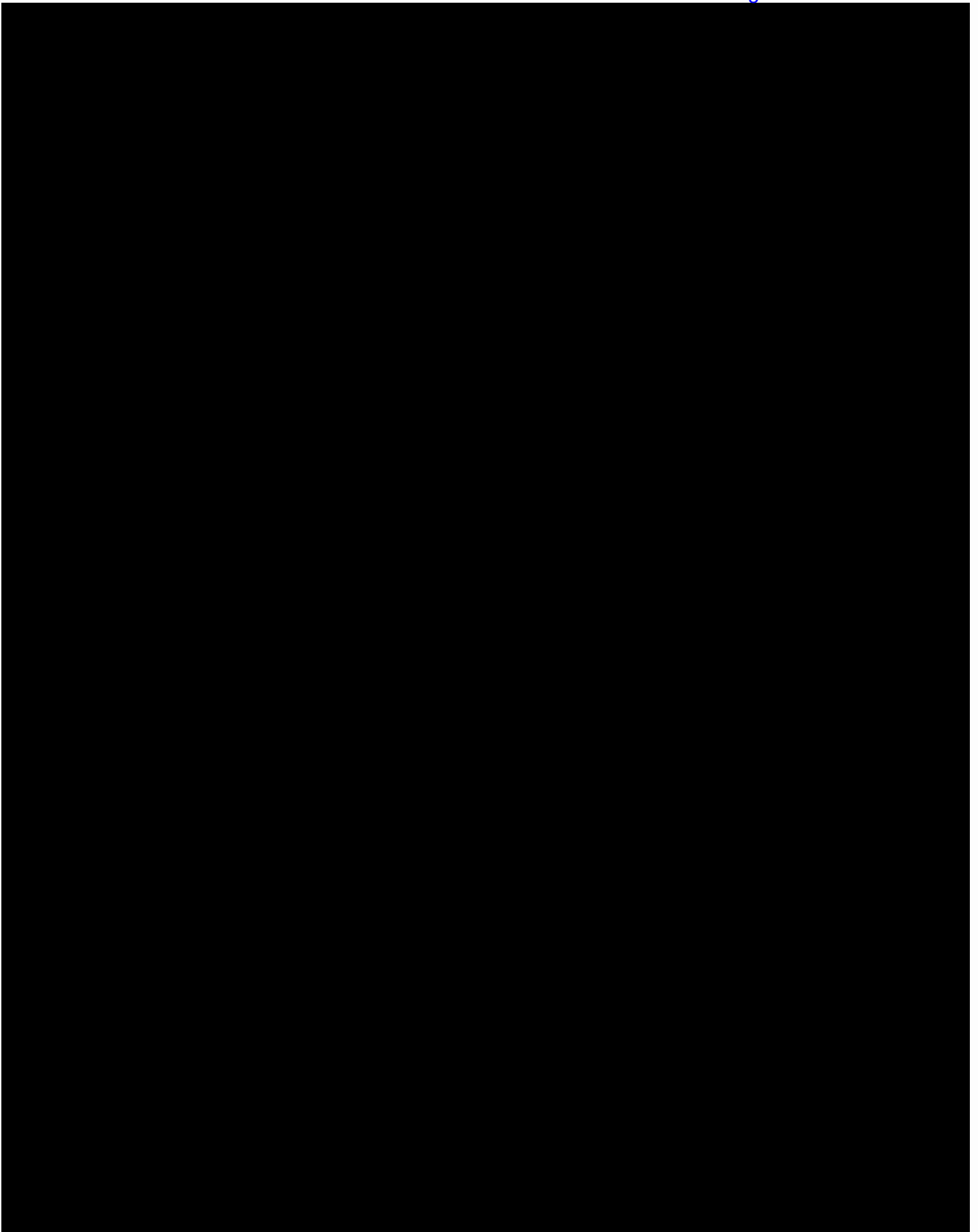


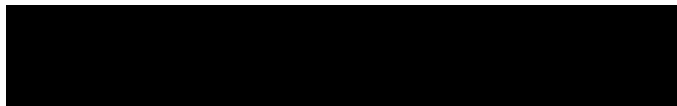
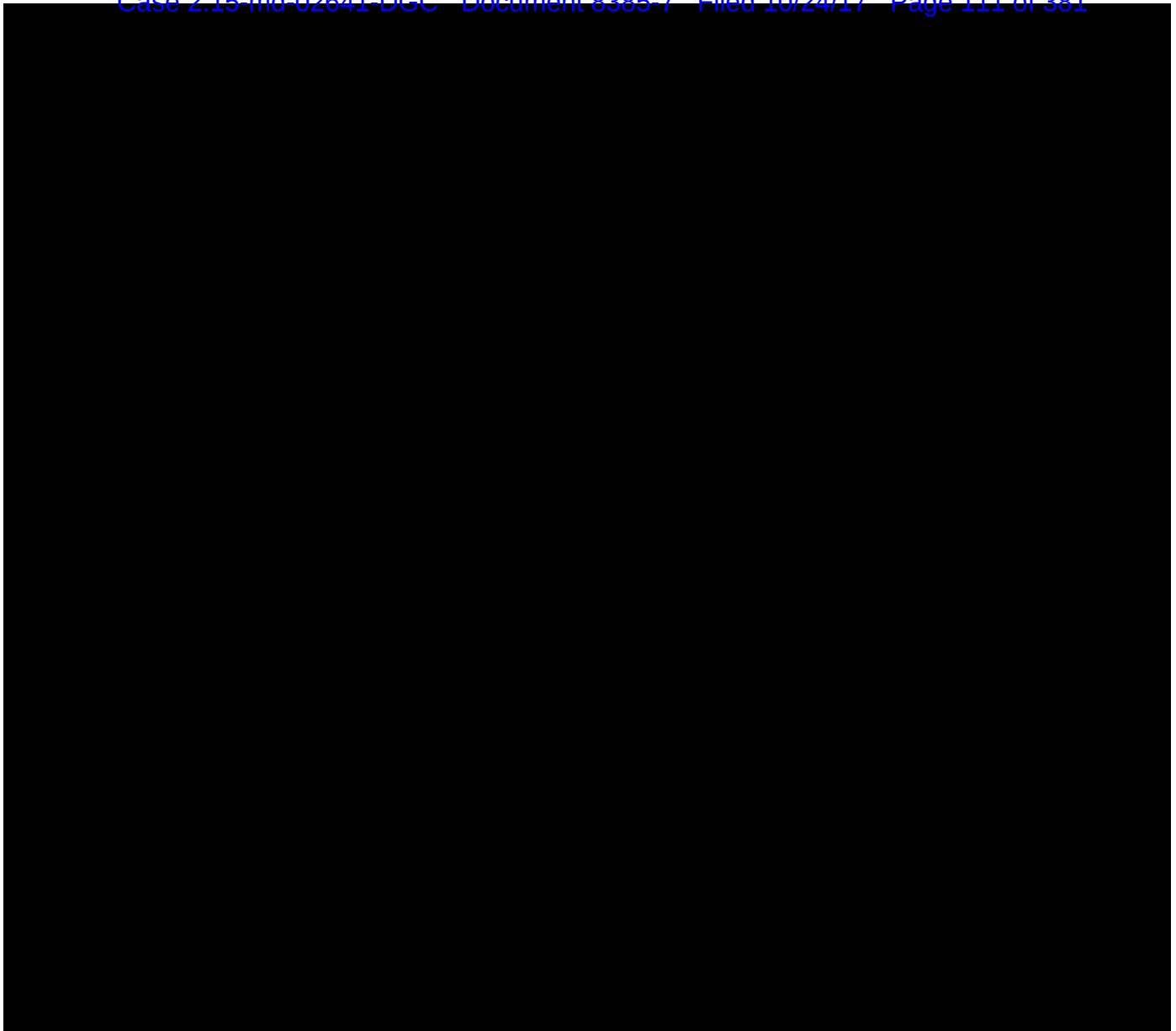


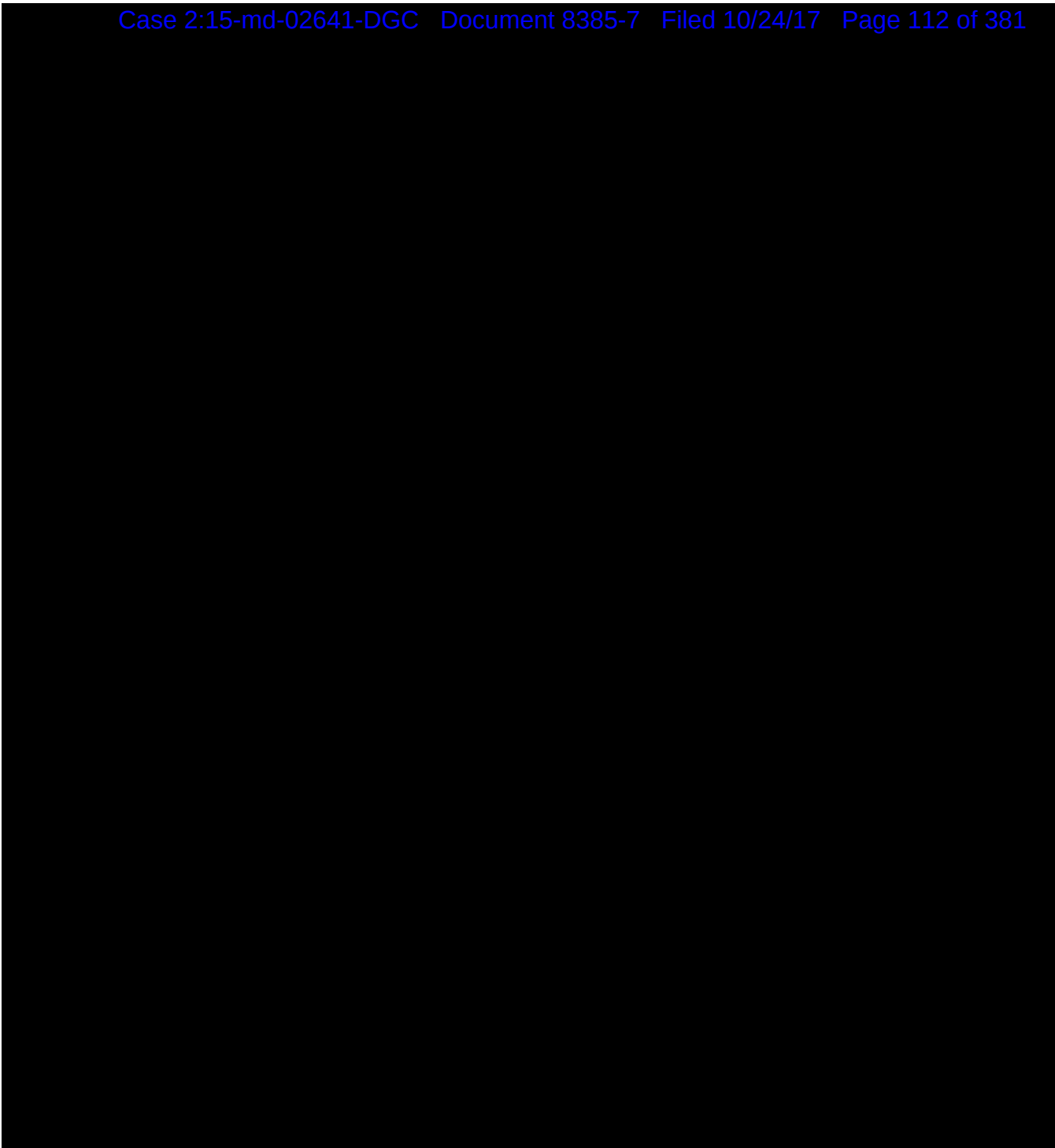




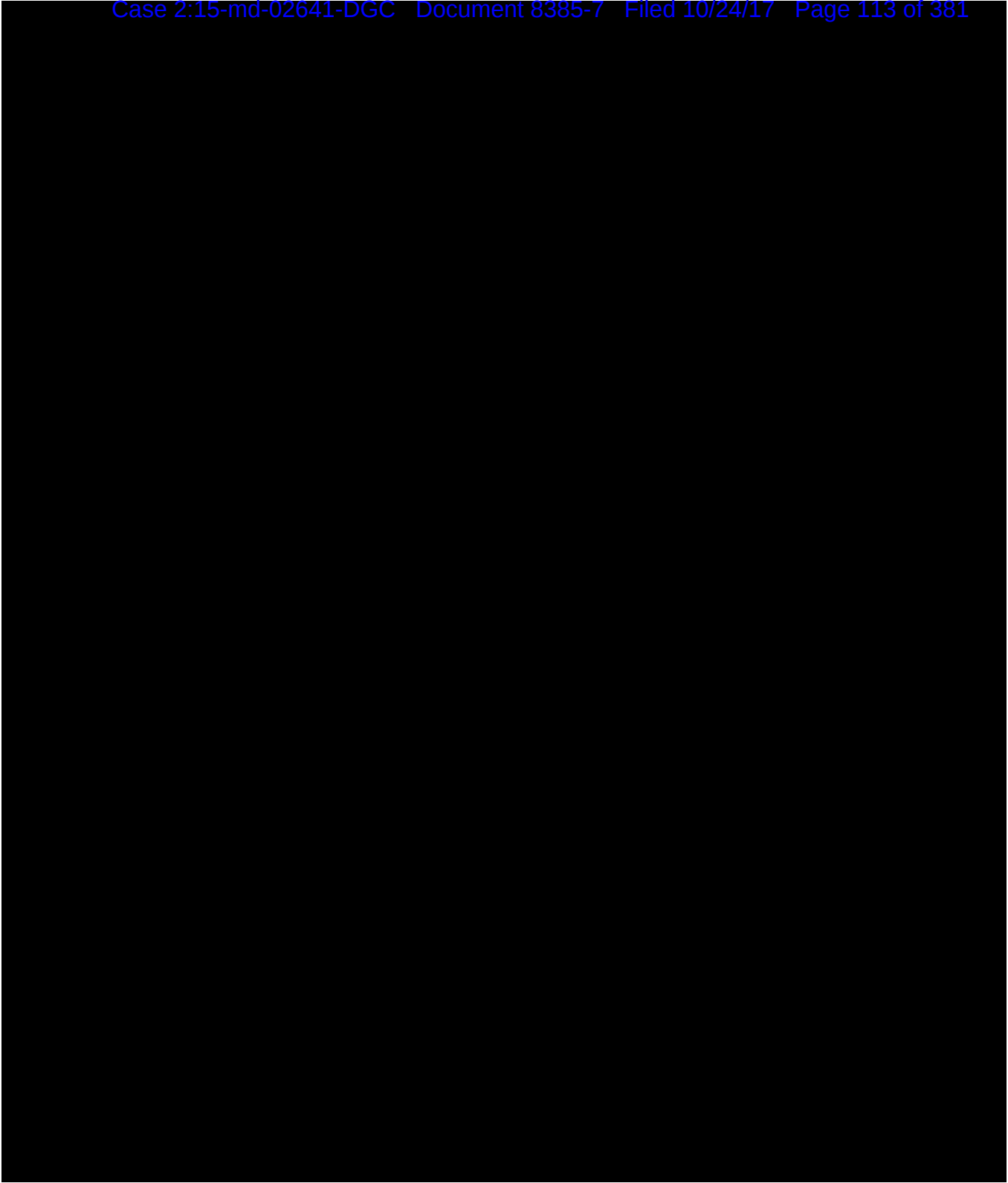








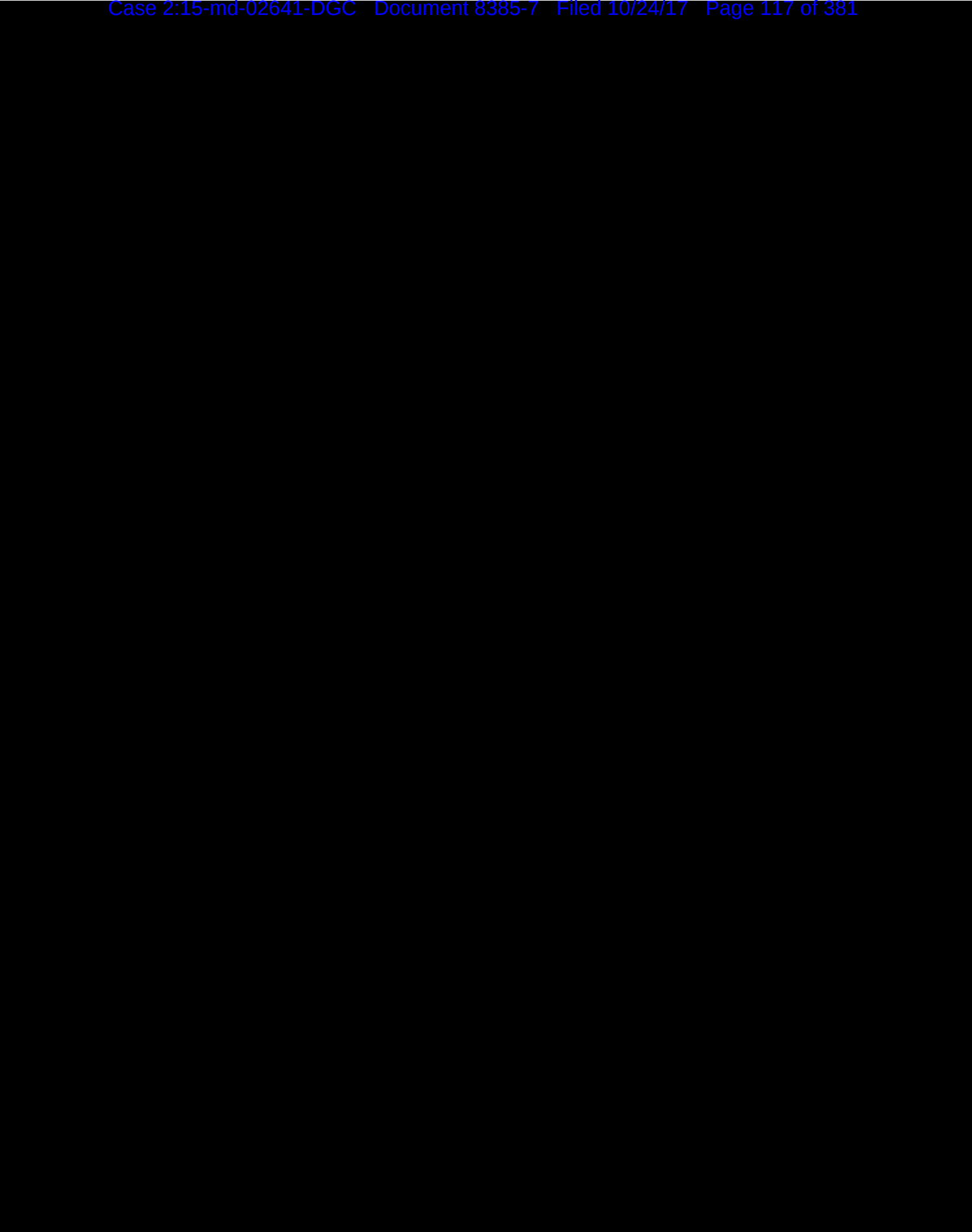


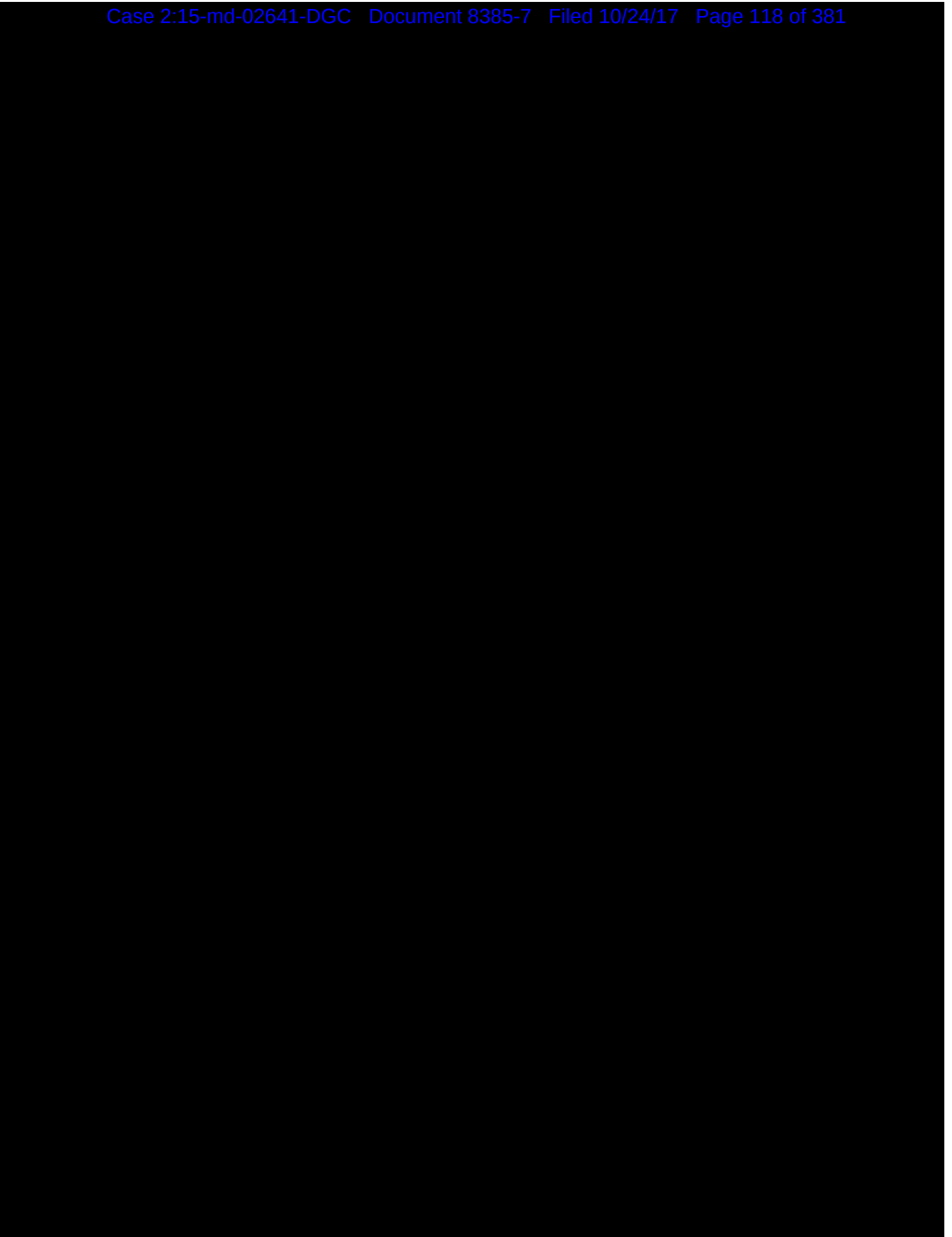




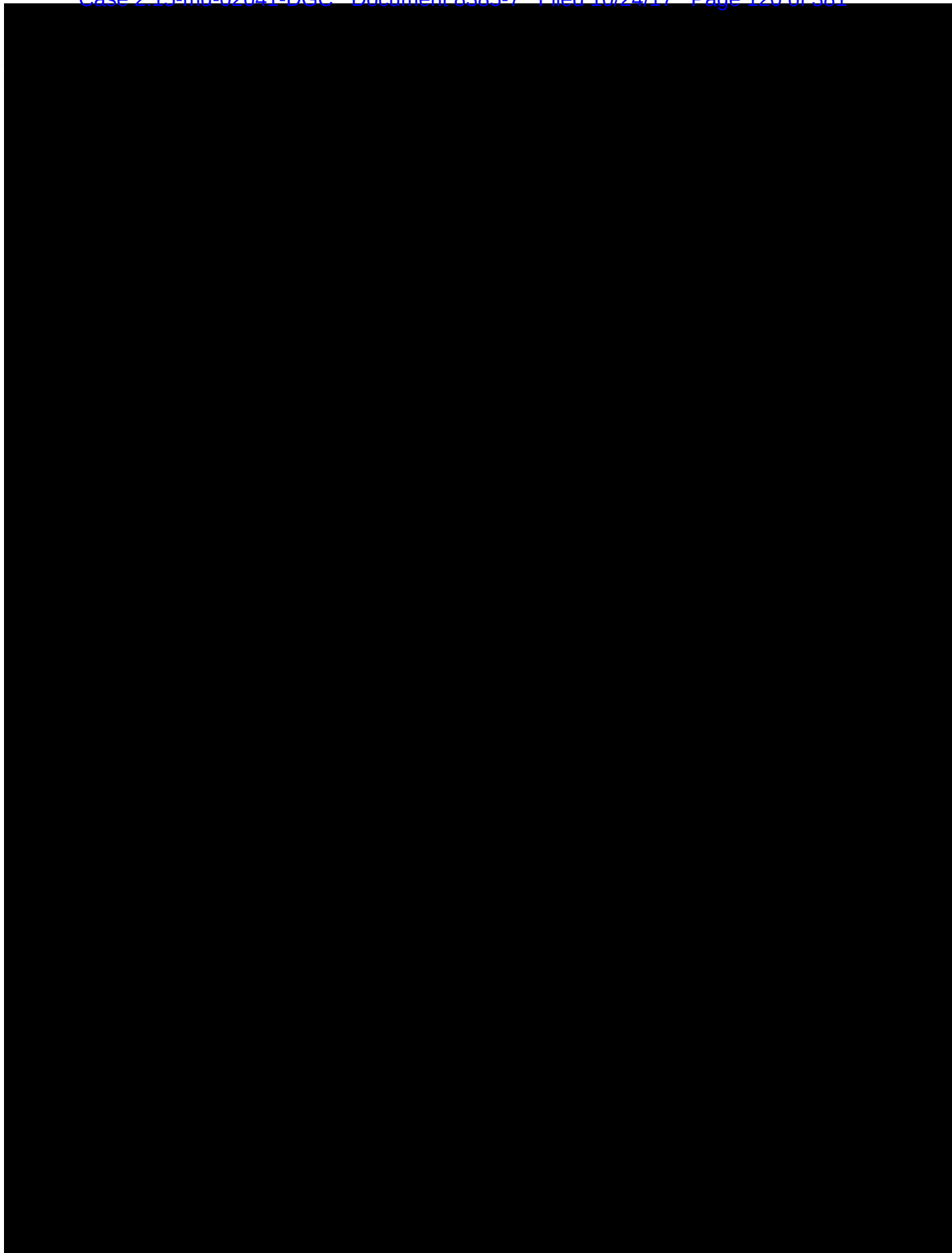




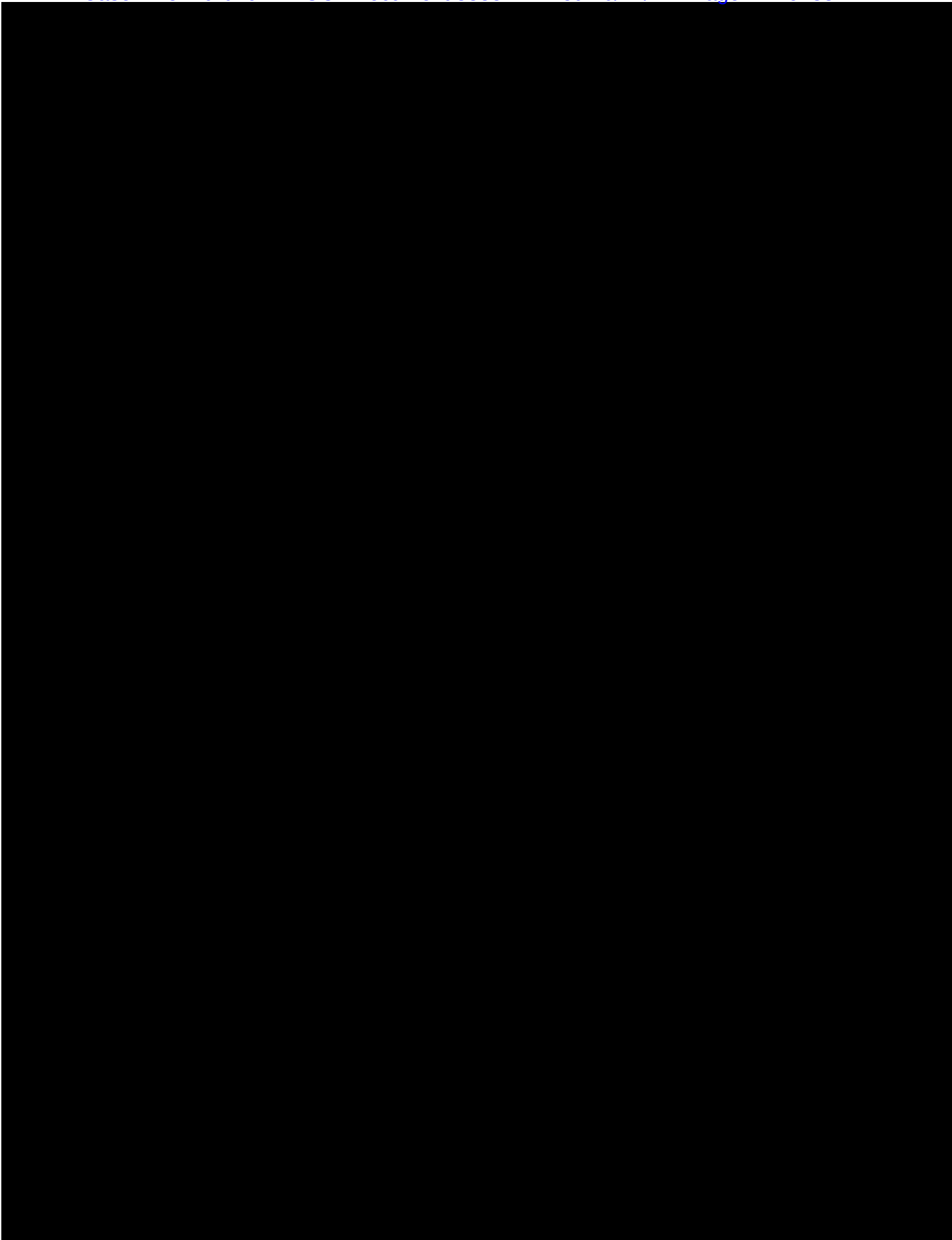


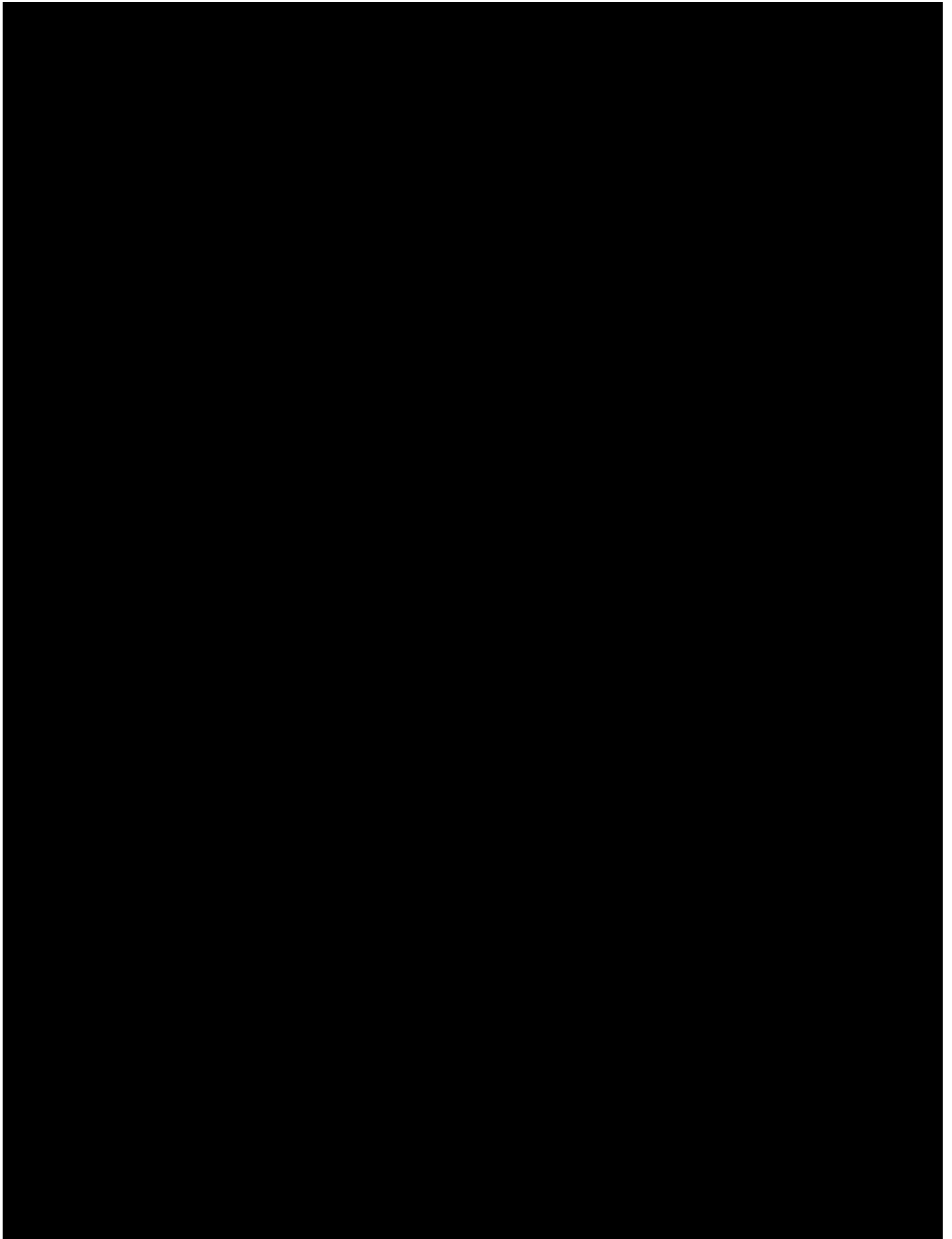






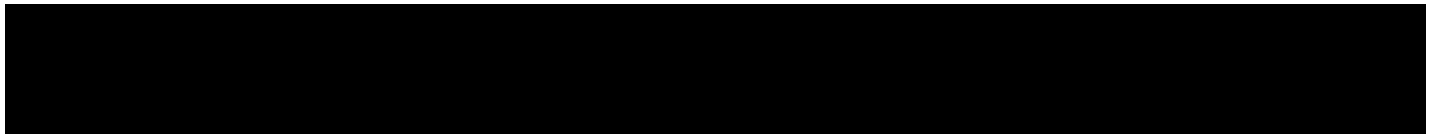
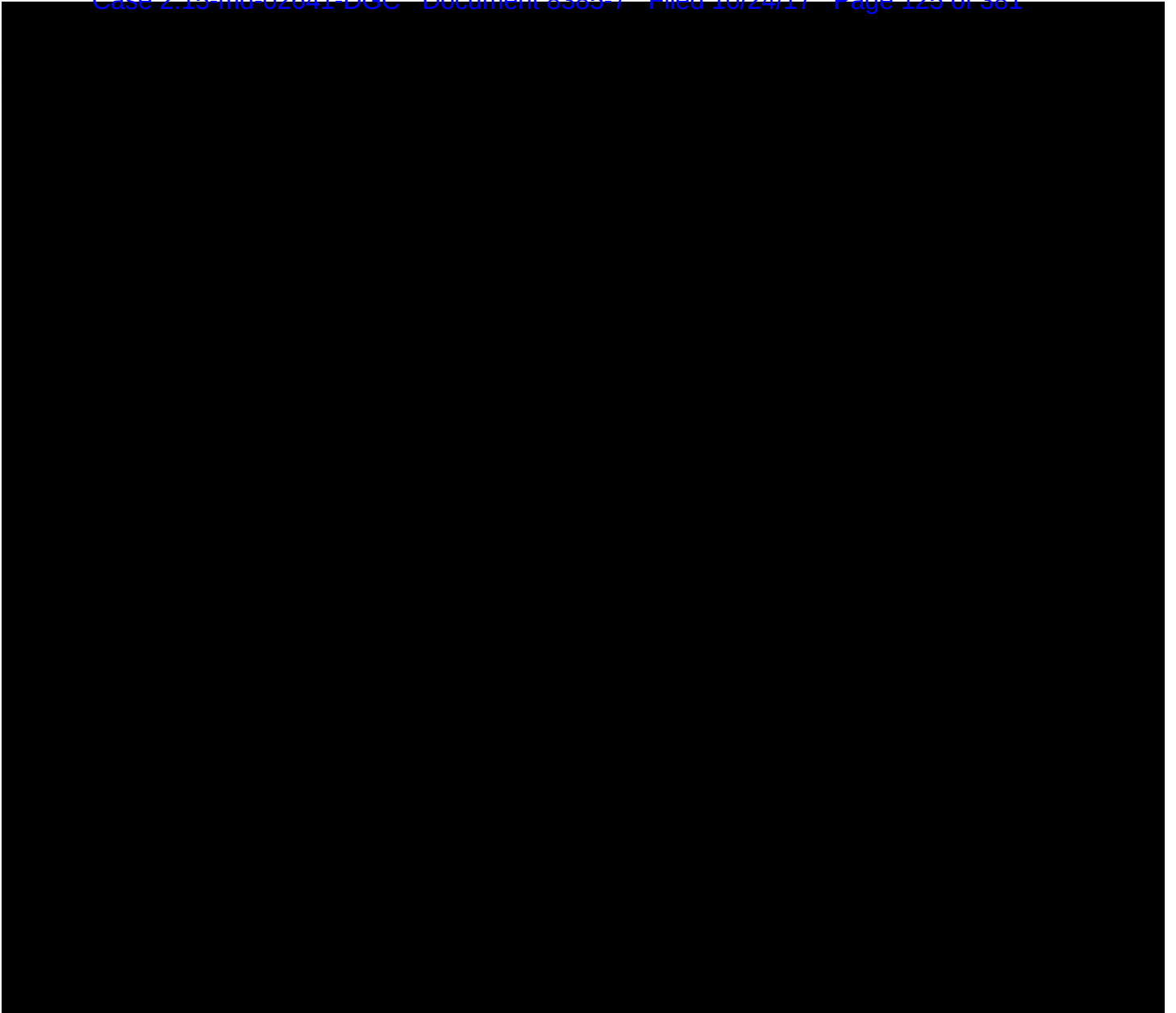










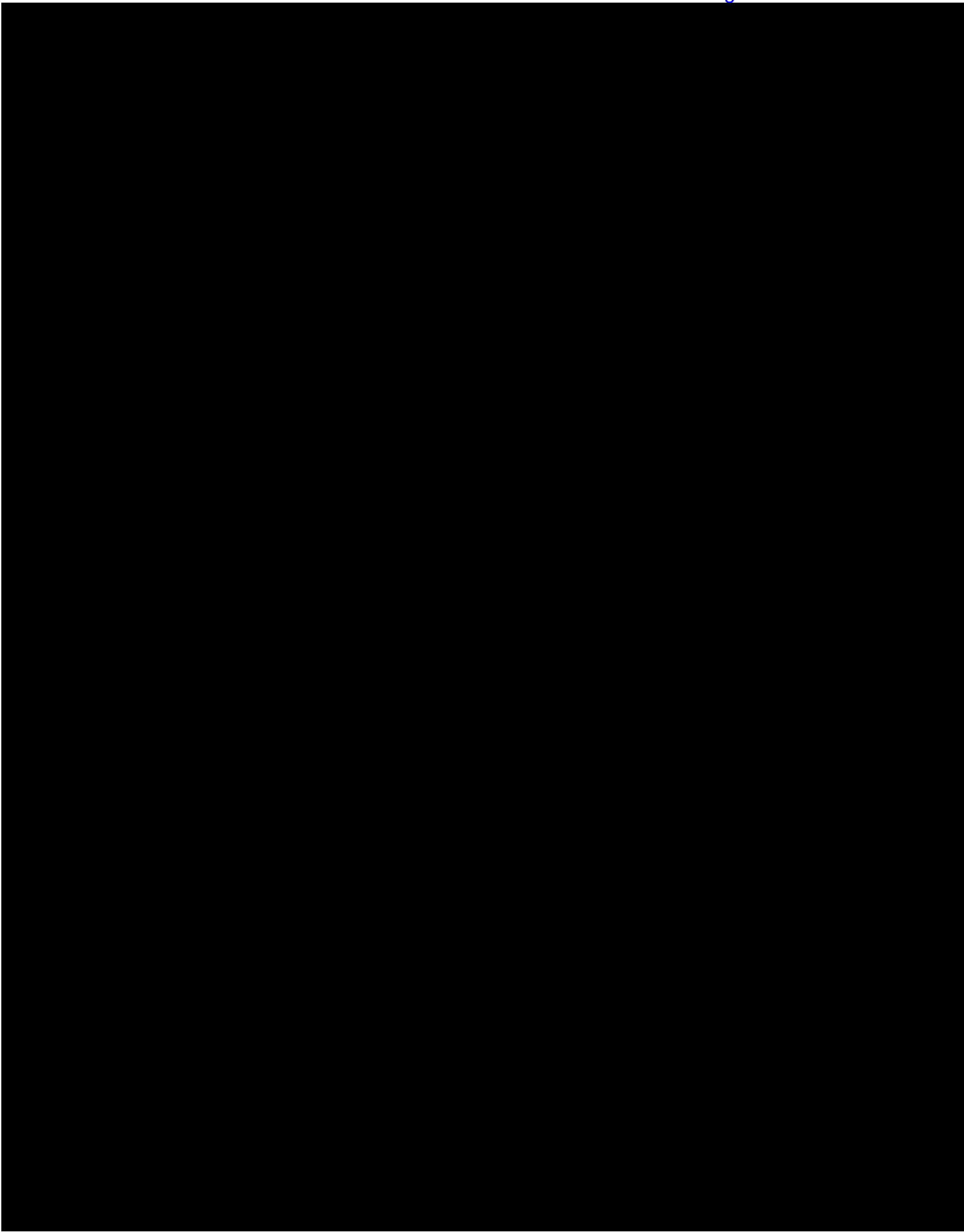




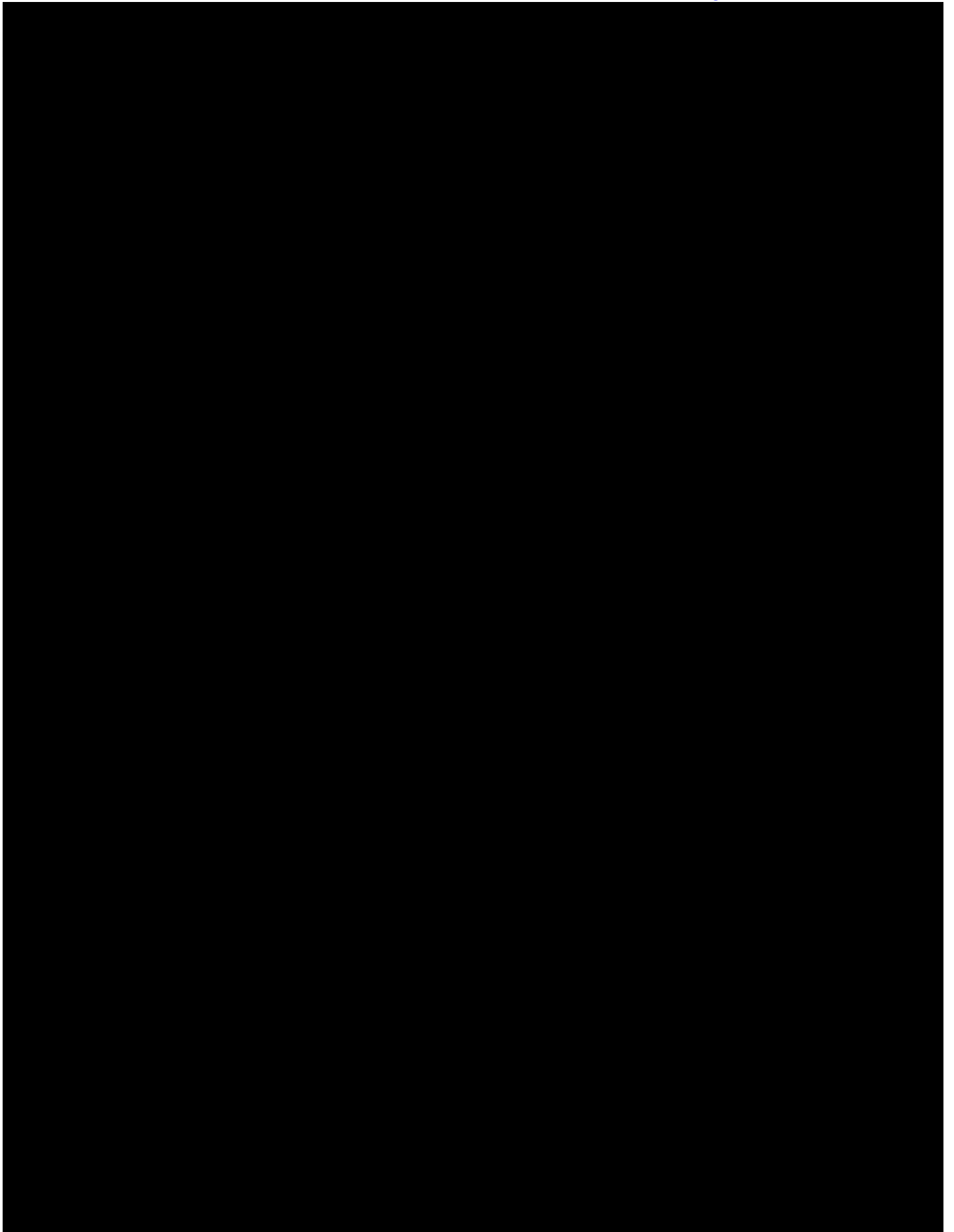










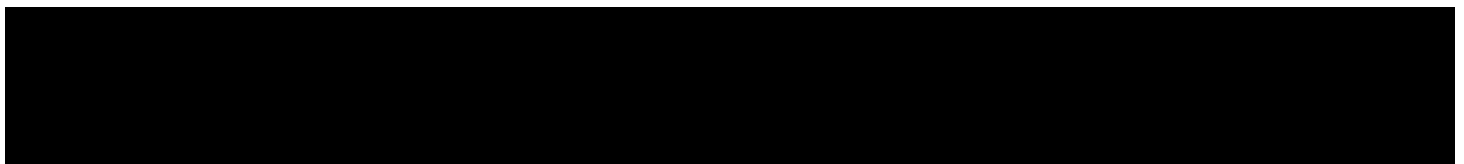




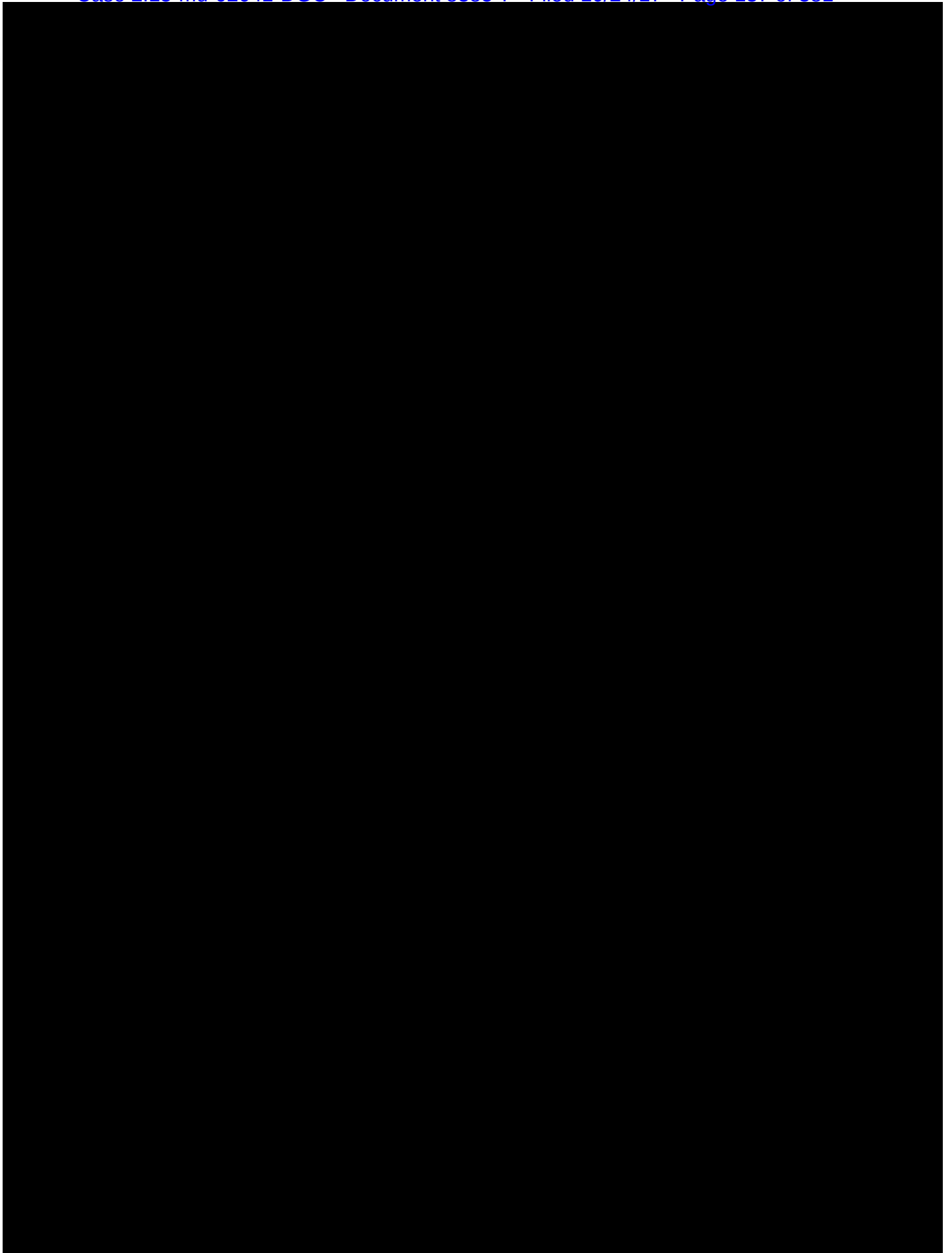


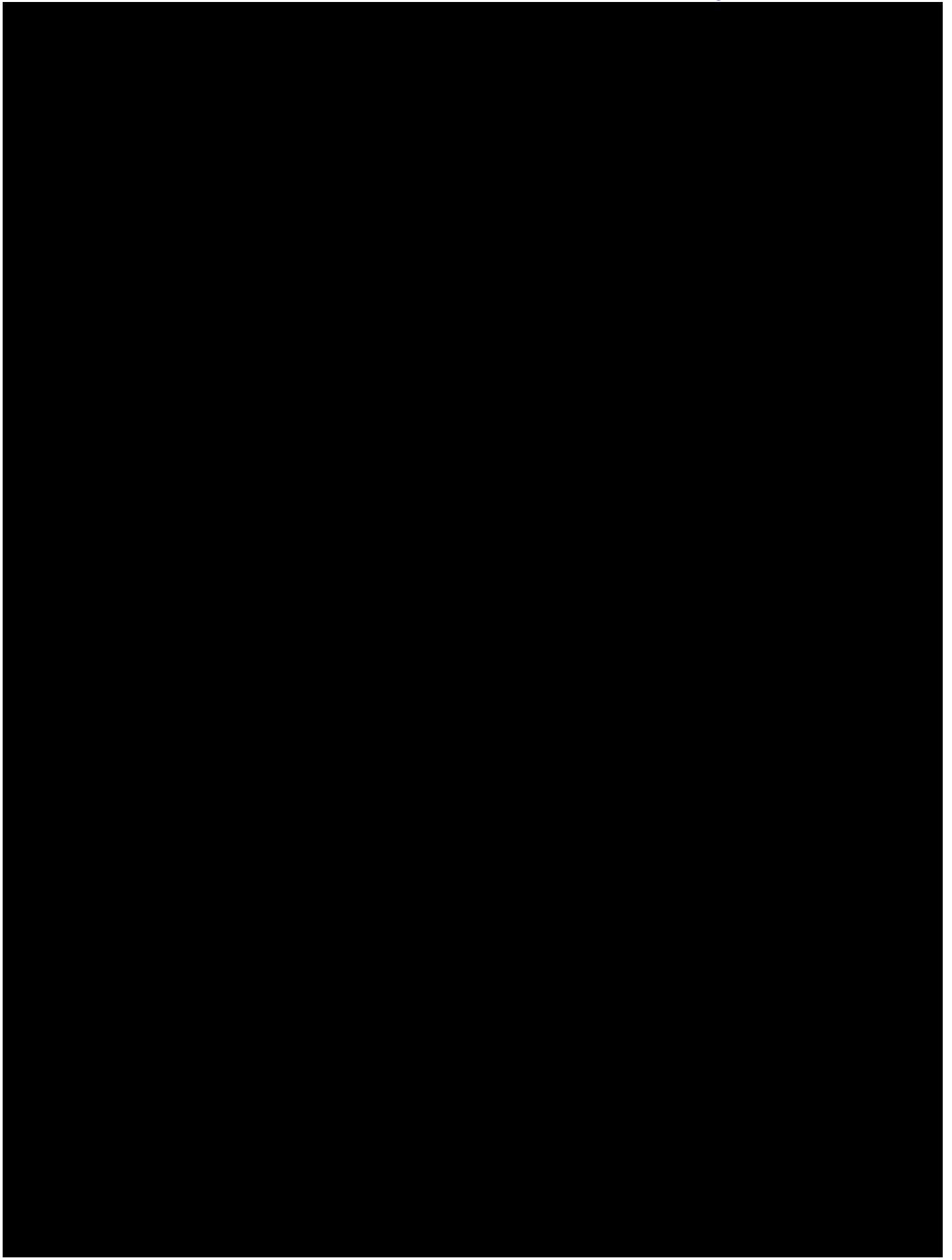


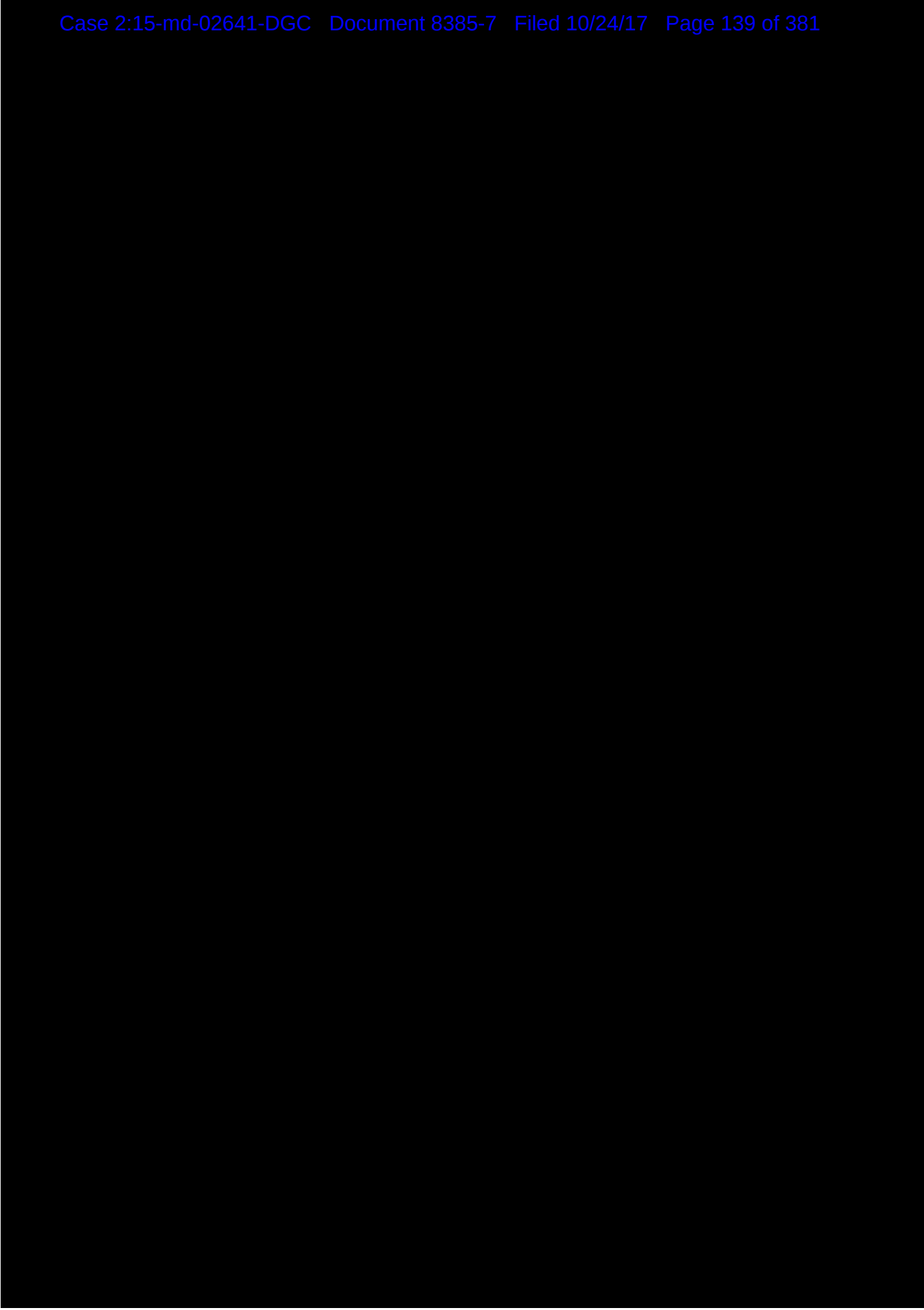




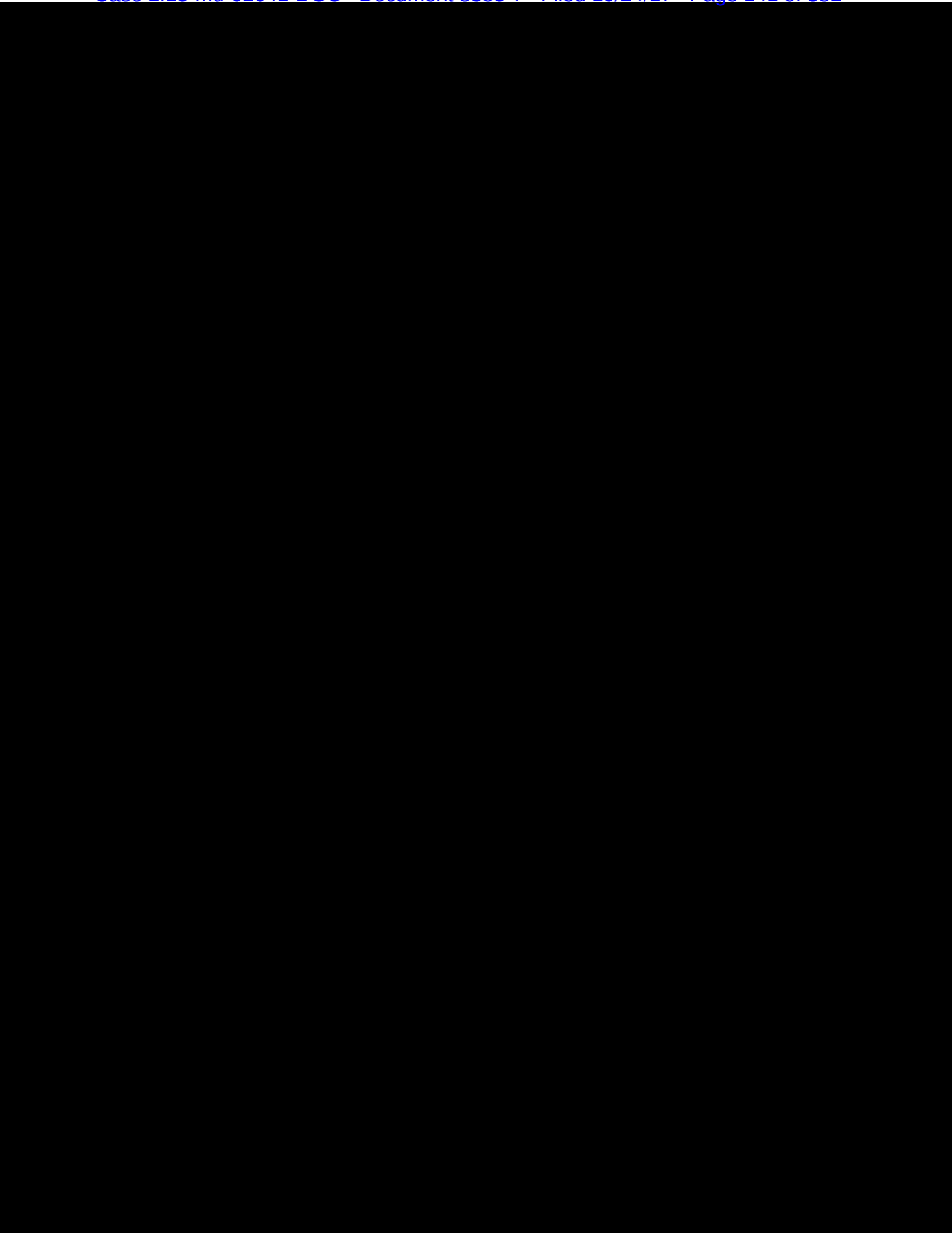


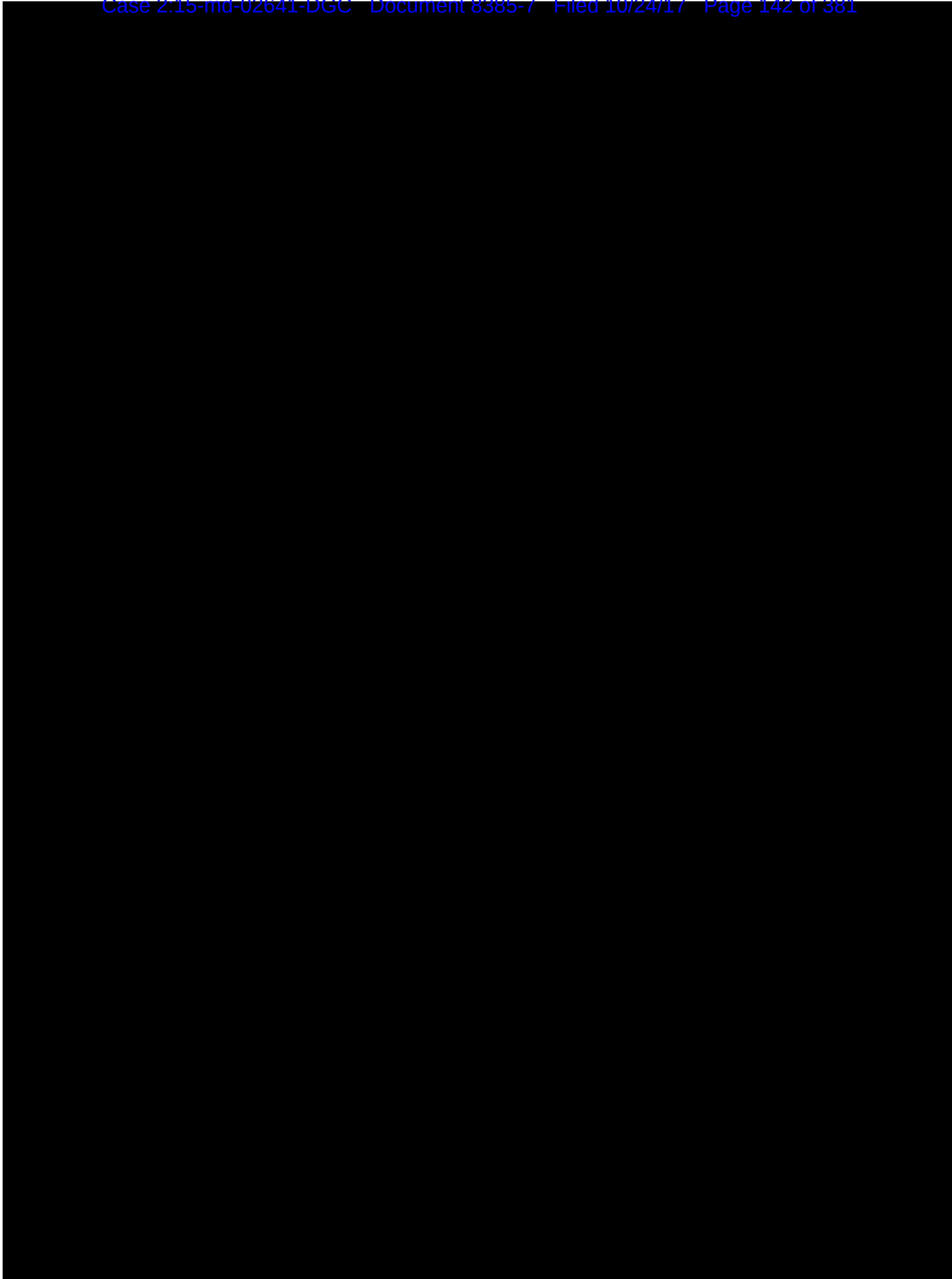




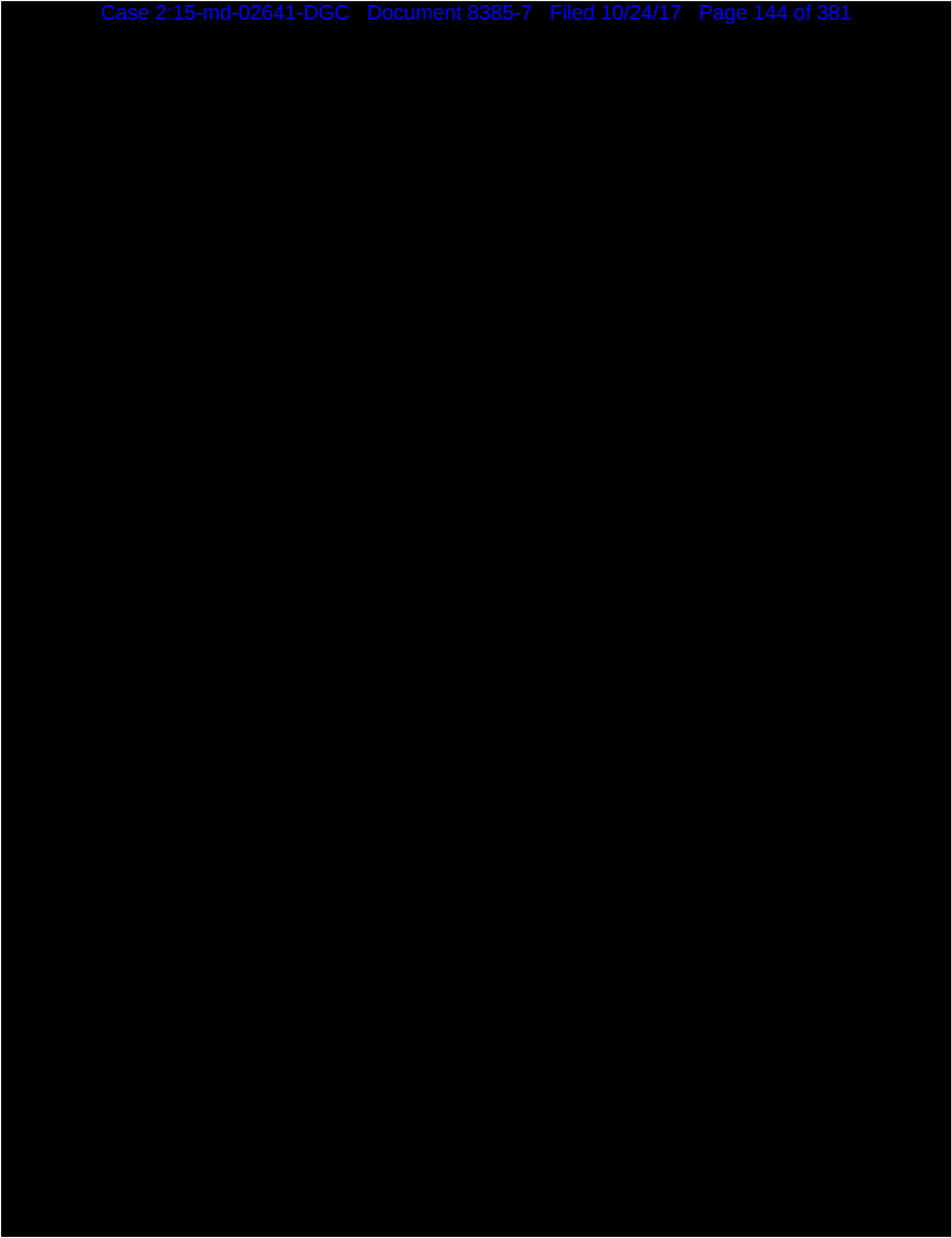




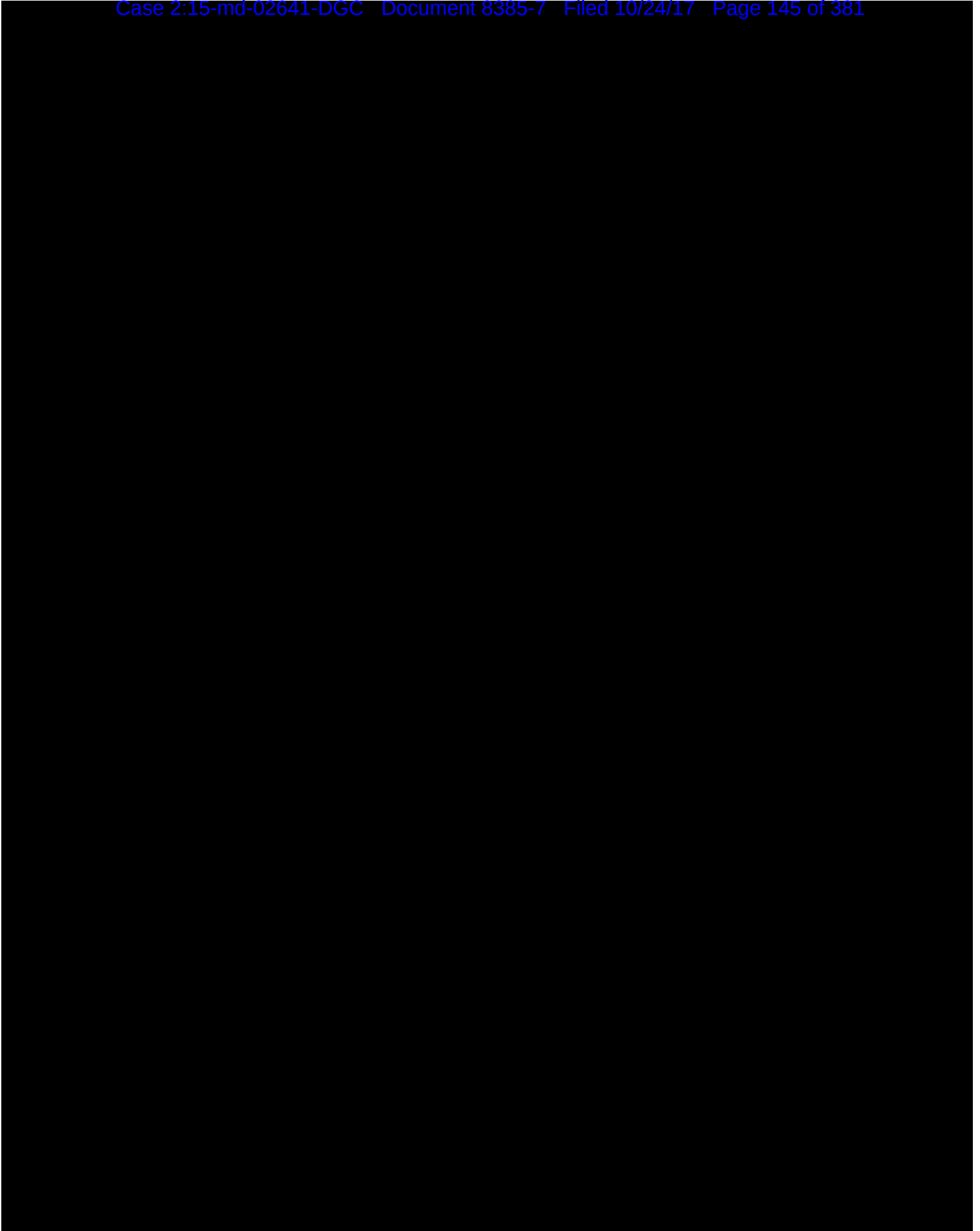














**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit H-B - REDACTED**

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UNITED STATES DISTRICT COURT  
DISTRICT OF ARIZONA

\* \* \* \* \*

In Re Bard IVC Filters Products  
Liability Litigation

No. MD-15-02641-PHX-DGC

\* \* \* \* \*

DO NOT DISCLOSE - SUBJECT TO FURTHER  
CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF [REDACTED]

TAKEN AT: Leib Knott Gaynor  
LOCATED AT: 219 North Milwaukee Street  
Milwaukee, WI

April 6, 2017  
10:07 a.m. to 12:28 p.m.  
REPORTED BY ANITA K. FOSS  
REGISTERED PROFESSIONAL REPORTER

\* \* \* \* \*

1 interventional radiology procedures during that 13  
2 to 14 years in Ohio?

3 A. Yes.

4 Q. About what percentage or practice, while  
5 you were in Ohio for those 14 years, was  
6 interventional radiology as opposed to general  
7 radiology?

8 A. Maybe 25 percent, 30 percent.

9 Q. Did that include implanting IVC filters?

10 A. Yes.

11 Q. Now, do you recall a patient of yours, my  
12 client, Lisa Hyde?

13 A. I do not.

14 Q. Have you had an opportunity to review any  
15 medical records to refresh your recollection about  
16 that patient?

17 A. I was here yesterday and I had -- I  
18 reviewed a one -- my -- I think my -- my report of  
19 the procedure.

20 Q. That procedure was what?

21 A. Placement of an IVC filter.

22 Q. Was it a G2X IVC filter?

23 A. I believe it may have been, but I'm not  
24 sure.

25 Q. Was that procedure -- or did that

1 Q. And then you also apply your knowledge as  
2 to what possible procedures or devices are  
3 available to treat that condition; right?

4 A. Yes.

5 MS. DALY: Objection. Objection,  
6 leading.

7 BY MR. SAELTZER:

8 Q. And Doctor, in coming and exercising your  
9 clinical discretion, do you perform a risk-benefit  
10 analysis?

11 A. I get an informed consent, which includes  
12 risks, benefits, and alternatives.

13 Q. When you are choosing which IVC filter to  
14 implant in a patient, can you describe for me what  
15 thought process you go to as to which filter you  
16 select from the various options that are out there  
17 in the marketplace?

18 MR. LEIB: We're talking about in or  
19 [REDACTED] as a custom and practice pertaining to  
20 your client, [REDACTED]

21 MR. SAELTZER: Yes, in and around  
22 February of 2011.

23 THE WITNESS: I look for any filter  
24 that's FDA approved, that I'm familiar with  
25 placing.

1 custom and practice at the time that he implanted  
2 on Mr. Saeltzer's patient -- client. So I didn't  
3 view it as invading privilege. It was historical  
4 as to his thought process. So that's why I didn't  
5 assert a privilege, and I wouldn't instruct him.

6 MS. DALY: I'm sorry, just again note my  
7 objection.

8 MR. LEIB: Yeah, okay. And Taylor, I  
9 just didn't want to -- the reason why I asked you  
10 to elaborate because I -- you know, I assume that  
11 you're going to be asking some questions, and I  
12 want to be, as I say, evenhanded as to asserting  
13 the privilege to make sure that I understand what  
14 your objection is so if other objections come down  
15 the pike during your questioning, you know, I'll  
16 instruct him evenly between both parties.

17 MS. DALY: Thank you.

18 BY MR. SAELTZER:

19 Q. Do you have the question in mind, Doctor?  
20 Would you like it read back to you?

21 A. I'm sorry, what am I being asked?

22 Q. That tells me we should probably read you  
23 the question. So we'll have the question read to  
24 you, Doctor.

25 COURT REPORTER: "[REDACTED]

1     [REDACTED], was it your understanding that all  
2     FDA-cleared IVC filters had the same performance?  
3     They all performed the same?"

4                 THE WITNESS: I think that they -- they  
5     were -- they were all very comparable.

6     BY MR. SAELTZER:

7                 Q. Did you believe that they were all  
8     comparable in terms of risk of complications, such  
9     as migrations or fractures?

10                A. Yes.

11                Q. Doctor, going back to your state of mind

12     [REDACTED]  
13     [REDACTED], if an IVC  
14     filter carried with it a significant potential for  
15     serious injury or death, that would be important  
16     information for you to know as a clinician?

17                MR. LEIB: Yeah, and I think that does  
18     call for an expert opinion, and I would instruct  
19     him not to answer. And I would invite you to  
20     re-frame the question to avoid invading the  
21     privilege and --

22                MS. DALY: Join in the objection.

23     BY MR. SAELTZER:

24                Q. So Doctor, I want to go -- again, we'll  
25     go back, we time travel back to your thought



1 MS. DALY: Same objections.

2 MR. LEIB: He doesn't want you to  
3 speculate. If you have to guess, you have to tell  
4 him. If you -- based upon the information you've  
5 been given, if you can state [REDACTED], you can  
6 go ahead and historically tell him that.

7 THE WITNESS: Right or wrong, I felt that  
8 the risks for all of the FDA-approvable devices  
9 were -- were reasonable and customary, and that I  
10 probably wouldn't have deferred or postponed the  
11 filter placement in a patient who I felt really  
12 needed it.

13 BY MR. SAELTZER:

14 Q. As I'm understanding your answer, right  
15 or wrong, you assumed that the complication rates  
16 among the FDA cleared or approved IVC filters was  
17 roughly equivalent?

18 A. Yes.

19 Q. If you had learned differently, that  
20 would be the type of information that you would  
21 have used in your clinical practice, true?

22 MS. DALY: Same objections.

23 THE WITNESS: I tend to trust the FDA  
24 more than individual companies.

25 BY MR. SAELTZER:

1 Q. Sure. Understanding that you have some  
2 more trust of the FDA than individual companies, if  
3 you actually learned that the complication rates  
4 among filters was not equivalent, even though they  
5 had all been cleared, that's the type of  
6 information, as a treating doctor, you would have  
7 been interested in and considered -- at least  
8 considered when making your treatment decisions?

9 MR. LEIB: Well --

10 MS. DALY: Objection. Same objection as  
11 before, leading, and now it's argumentative.

12 MR. LEIB: It's -- it's clearly a  
13 hypothetical, but I think unless it's tethered to  
14 this patient, it is invading the privilege. So I  
15 would invite you to rephrase it to tether it this  
16 to patient.

17 BY MR. SAELTZER:

18 Q. And I had intended to mean that's the  
19 type of information you would have considered in  
20 making your treatment decision for [REDACTED]

21 MR. LEIB: Okay. If you know that, you  
22 can say yes. And if you don't know, you say you  
23 don't know. If you have to speculate -- he doesn't  
24 want you to guess at any of these answers.

25 THE WITNESS: Yeah, I don't know.

1 that would have been something he would have  
2 factored into his clinical judgment.

3 MR. LEIB: You've tethered it to the  
4 article, that's the problem. The form of the  
5 question invades his privilege, and that's why I'm  
6 instructing him not to answer.

7 BY MR. SAELTZER:

8 Q. If Bard knew that the G2X filter [REDACTED]  
[REDACTED] was not performing as well as  
10 the other competitors' IVC filters, and it knew  
11 that before [REDACTED] [REDACTED] is that the type of  
12 information you would have considered if Bard had  
13 brought that to your attention?

14 MS. DALY: Same objection.

15 THE WITNESS: I don't particularly pay  
16 attention to everything that's published or comes  
17 my way. And so if I had read the article, I -- I  
18 may or may not have been swayed by its contents.

19 BY MR. SAELTZER:

20 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

24 [REDACTED]

[REDACTED]

[illegible]

1 in addition to the medication?

2           A.     Well, we're not always certain how the  
3     body will react to blood thinning medication.  And  
4     if the patient has a pattern of -- of getting  
5     clots, there's concern that one more clot could --  
6     could be devastating.  You err on the side of  
7     caution, and you want to make sure that somehow the  
8     patient is protected.  And henceforth the notion of  
9     a filter would serve that purpose.

10 Q. Somewhat of a belt-and-suspenders  
11 approach here with the medicine and the filter?

12                    A.     Yes.

[illegible]



1 is that true?

2 A. Yes.

3 Q. Did you ever have an opportunity to read  
4 the instructions for use document that accompanied  
5 the Bard G2X filter [REDACTED]

7 A. Yes.

8 Q. Are you aware that the IFU, or the  
9 instructions for use for that filter, lists, among  
10 the complications that -- that may occur, fracture,  
11 movement, and perforation of the filter?

12 A. Could you repeat the first part of the  
13 question? Am I --

14 Q. Yes. Are you aware that the instructions  
15 for use includes a section on complications that  
16 one might experience with a Bard G2X filter?

17 A. Yes.

18 Q. And that that -- those precautions  
19 included what we just talked about with  
20 complications, which would be fracture, movement of  
21 the filter, embolization of filter fragment pieces?

22 A. Yes.

23 Q. And also that the filter can perforate;  
24 correct?

25 MR. LEIB: The question is --

**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit H-C - REDACTED**



**Lisa A. Hyde**

**Vol. 1**

**01/25/2017**

1           A     If they did, I don't remember. The only  
2     thing I heard was IVC filters.

3           Q     About how many commercials would you say you  
4     saw before you found out your filter fractured?

5           A     I have no idea.

6           Q     Did you ever contact any attorneys in  
7     response to the advertisement you saw?

8           A     No.

9           Q     How did your husband come to find O'Steen  
10    and Harrison, those attorneys?

11          A     I thought he had found it from an attorney  
12    that he knew, but I believe he just Googled on his own  
13    and found this company.

14          Q     And where are they located, I'm sorry.

15          A     O'Steen?

16          Q     Yes.

17          A     Phoenix.

18          Q     Now, let's just discuss some of your  
19    background information. What is your date of birth?

20          A     [REDACTED]

21          Q     And where were you born?

22          A     [REDACTED]

23          Q     What is your ethnicity?

24          A     [REDACTED]

25          Q     And where did you grow up?

**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit H-D - REDACTED**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA**

*MDL No. 2641*

*In Re Bard IVC Filter Products Liability Litigation*

---

**PLAINTIFF FACT SHEET**

Each plaintiff who allegedly suffered injury as a result of a Bard Inferior Vena Cava Filter must complete the following Plaintiff Fact Sheet (“Plaintiff Fact Sheet”). In completing this Fact Sheet, you are **under oath and must answer every question**. You must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details as requested, please provide as much information as you can and then state that your answer is incomplete and explain why, as appropriate. If you select an “I Don’t Know” answer, please state all that you do know about that subject. If any information you need to complete any part of the Fact Sheet is in the possession of your attorney, please consult with your attorney so that you can fully and accurately respond to the questions set out below. If you are completing the Fact Sheet for someone who cannot complete the Fact Sheet for himself/herself, please answer as completely as you can.

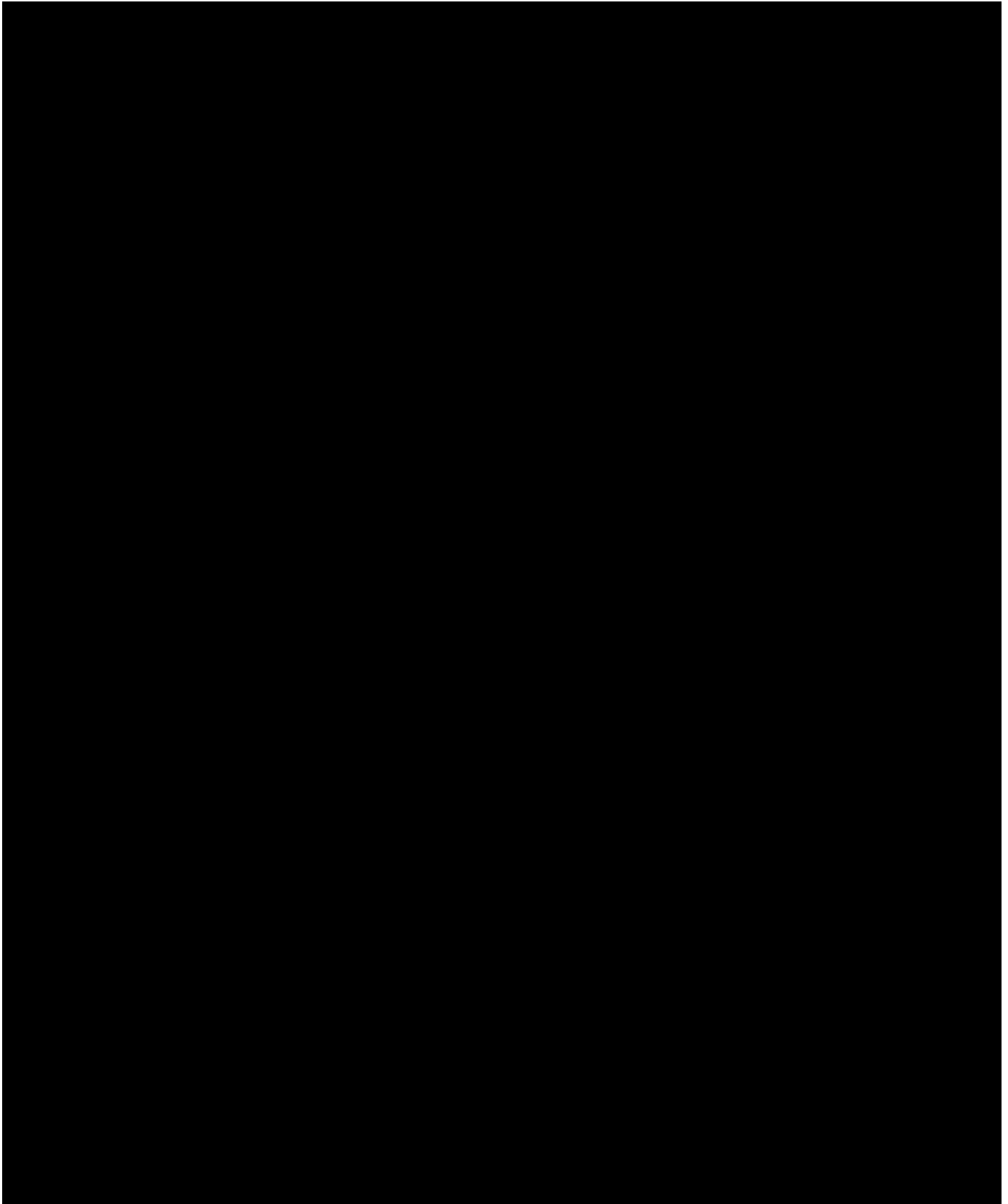
The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and responses to requests for production pursuant to Fed. R. Civ. P. 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. Therefore, you must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production of documents contained in this Fact Sheet are non-objectionable and shall be answered without objection. This Fact Sheet shall not preclude Bard Defendants from seeking additional documents and information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

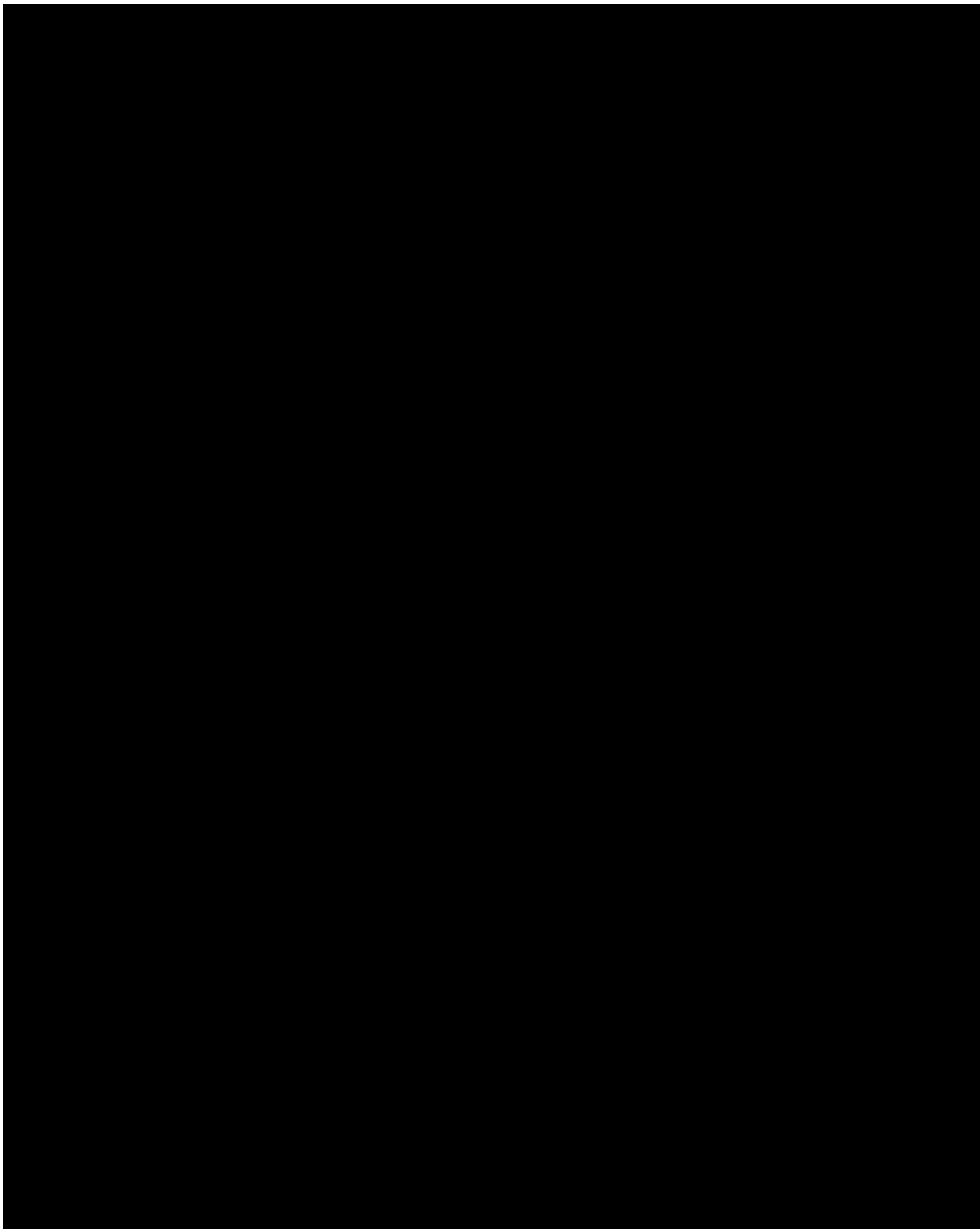
In filling out this form, “healthcare provider” shall mean any medical provider, doctor, physician, surgeon, pharmacist, hospital, clinic, medical center, physician's office, infirmary, medical/diagnostic laboratory, or any other facility that provides medical care or advice, along with any pharmacy, x-ray department, radiology department, laboratory, physical therapist/physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in your diagnosis, care and/or treatment.

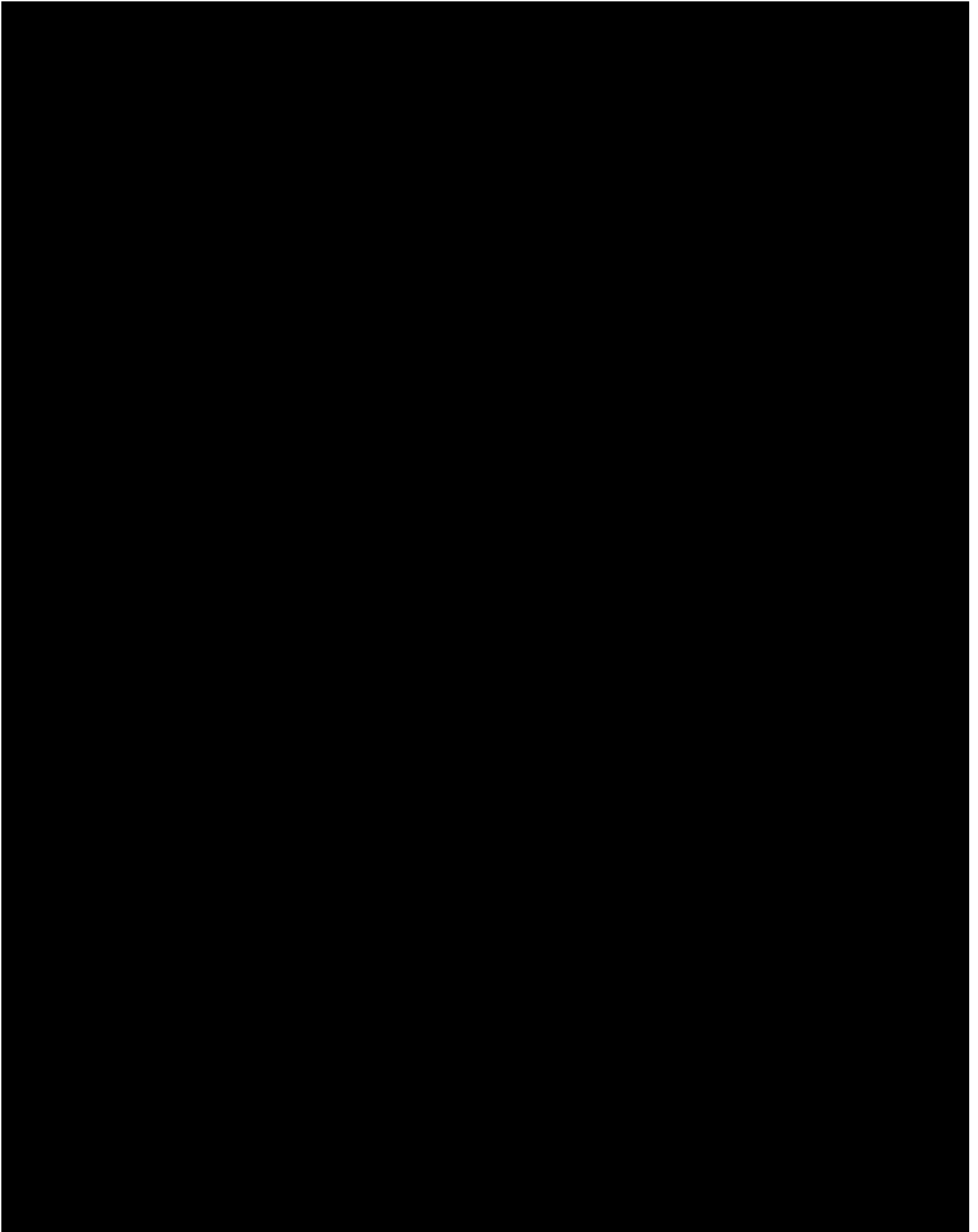
In filling out this form, the terms “You” or “Your” refer to the person who received a Bard Inferior Vena Cava Filter manufactured and/or distributed by C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. (“Bard Defendants”) and who is identified in Question 1(a) below.

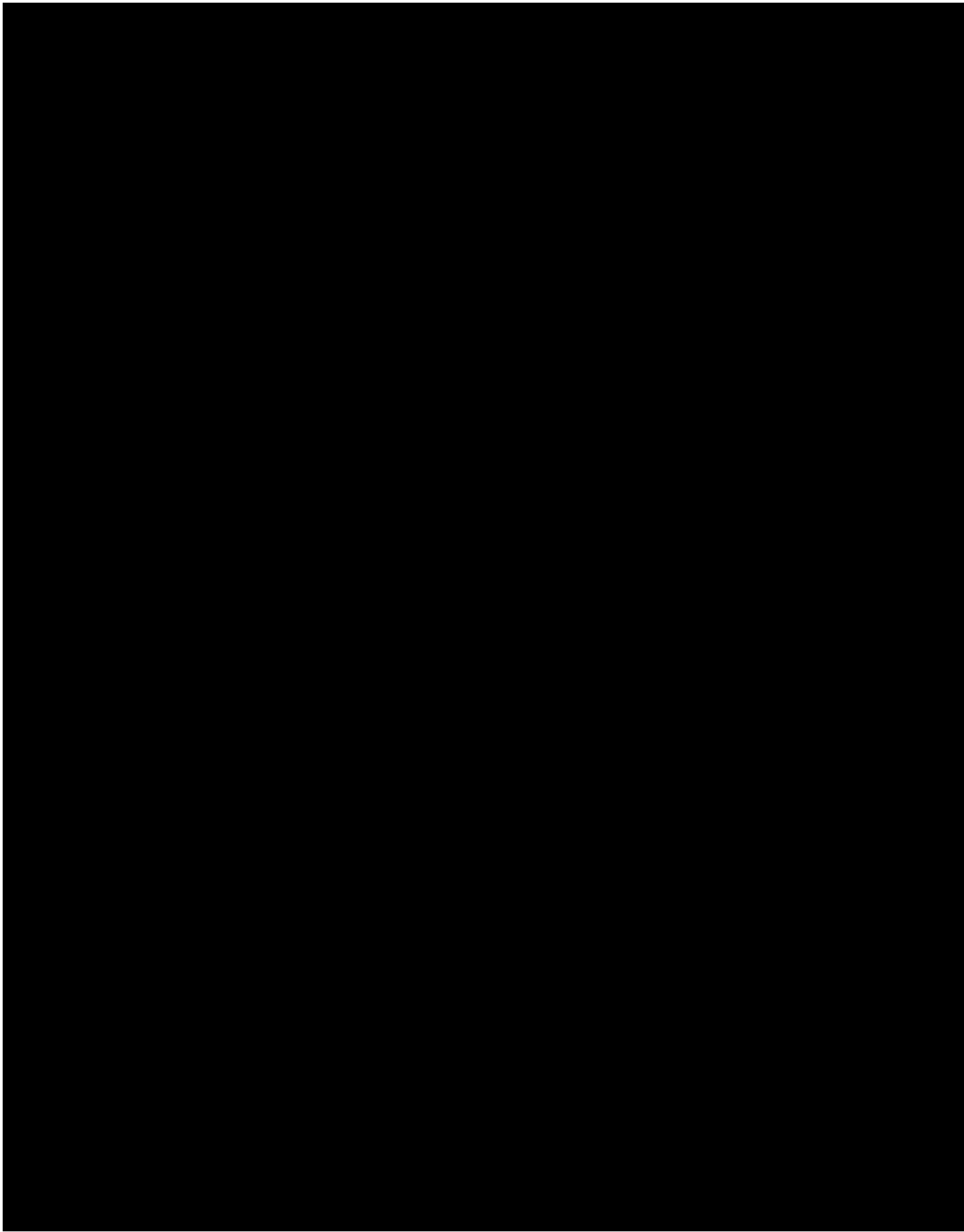
To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary, Information provided by Plaintiff will only

be used for the purposes related to this litigation and may be disclosed only as permitted under the protective order in this litigation.

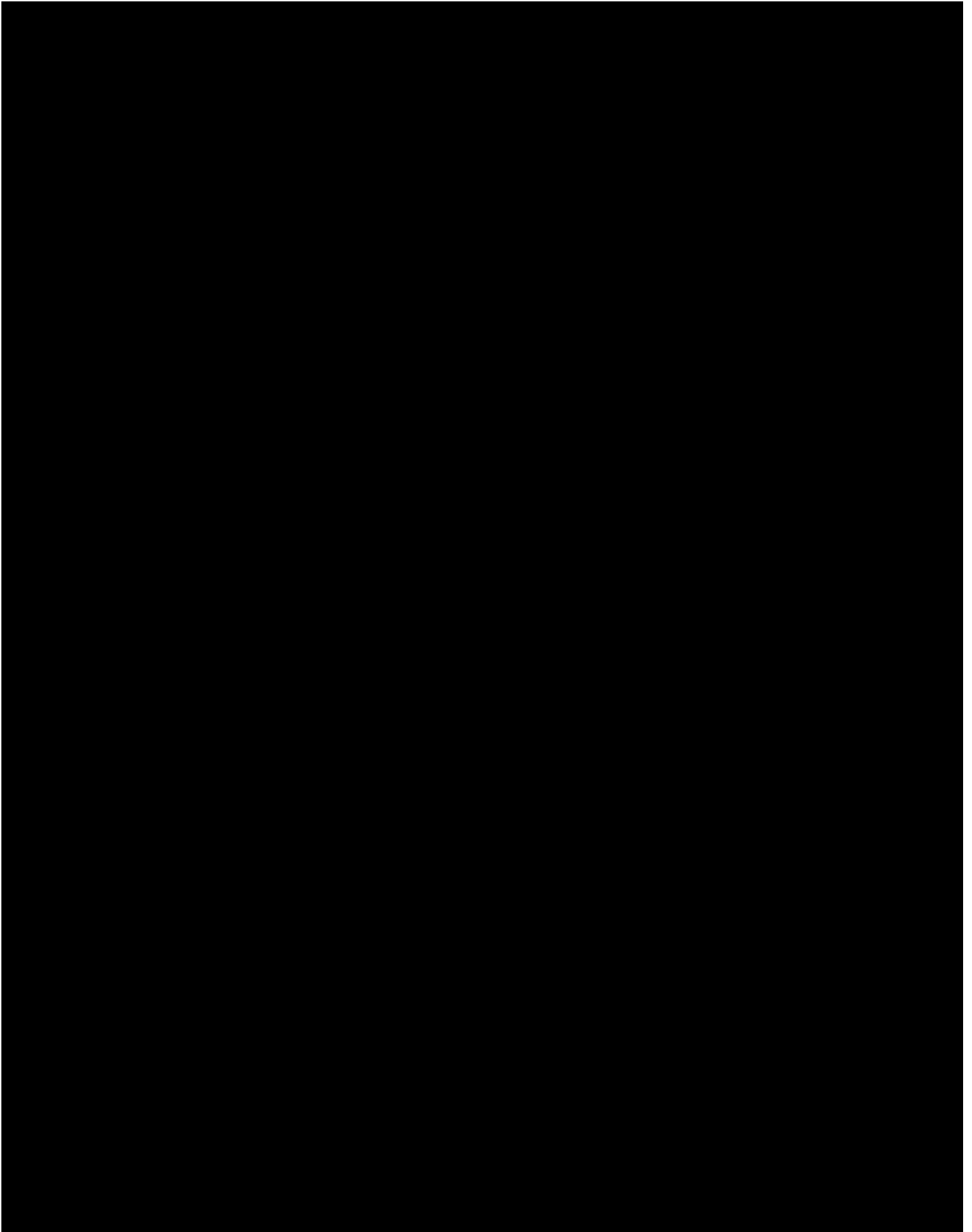


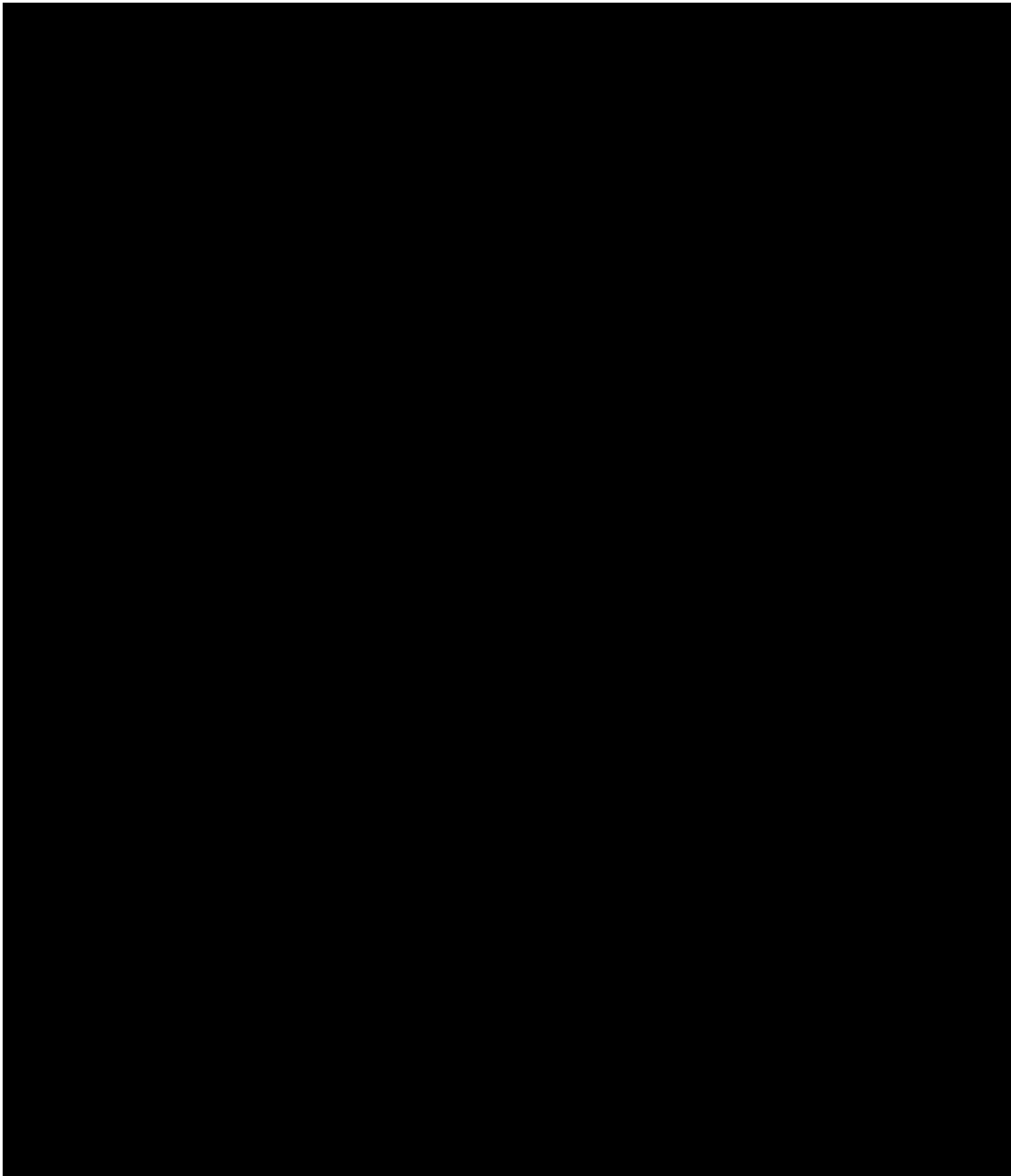


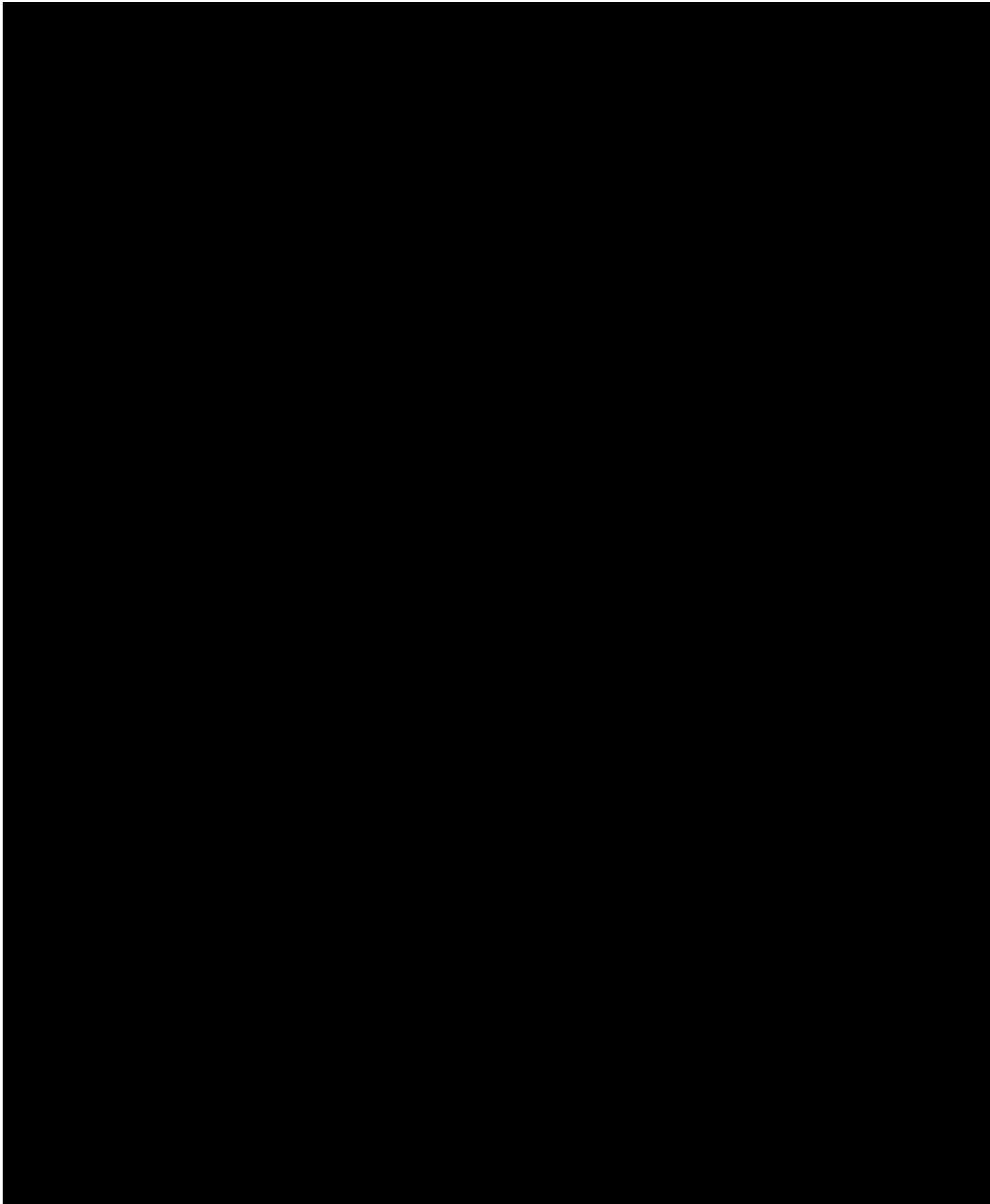


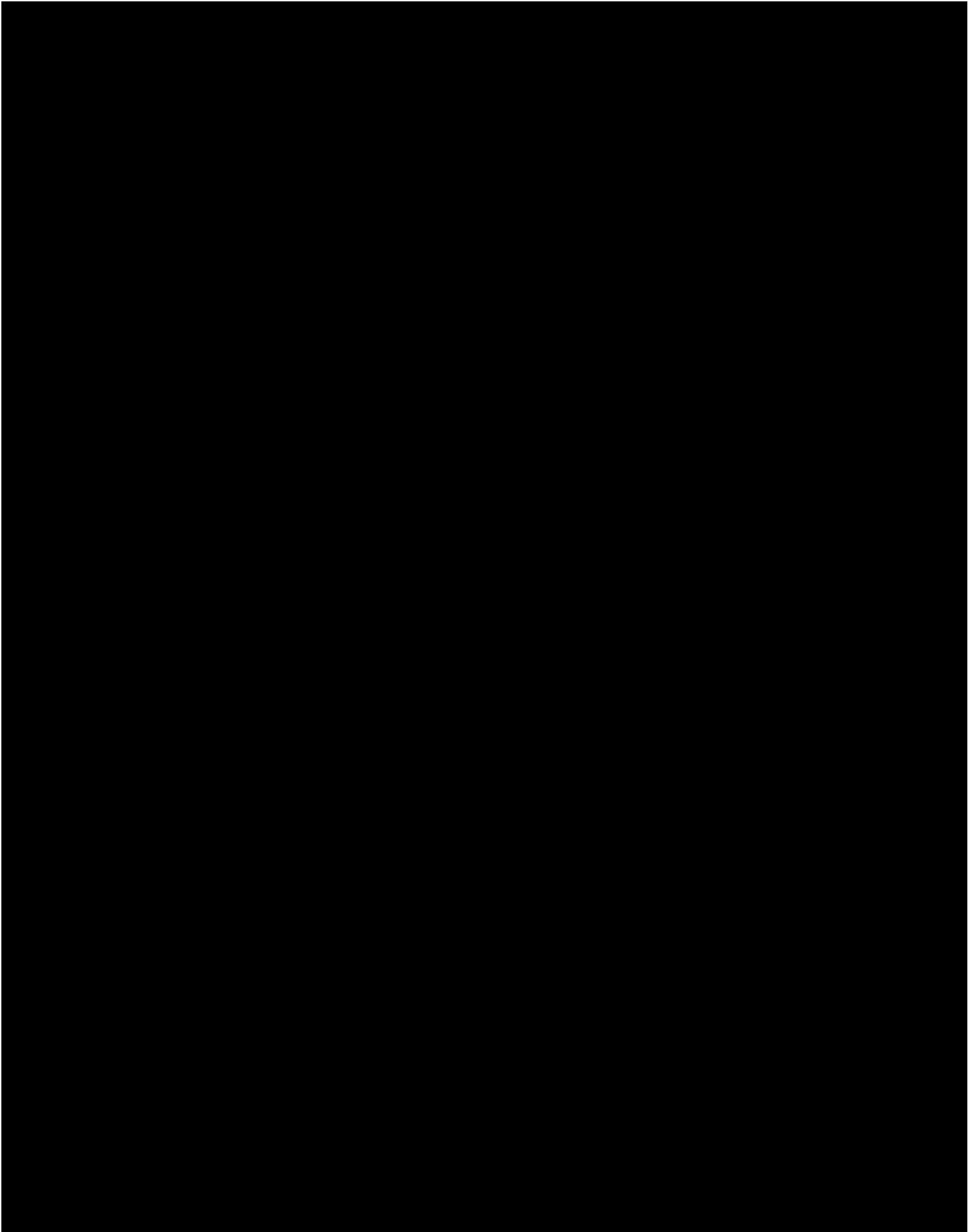


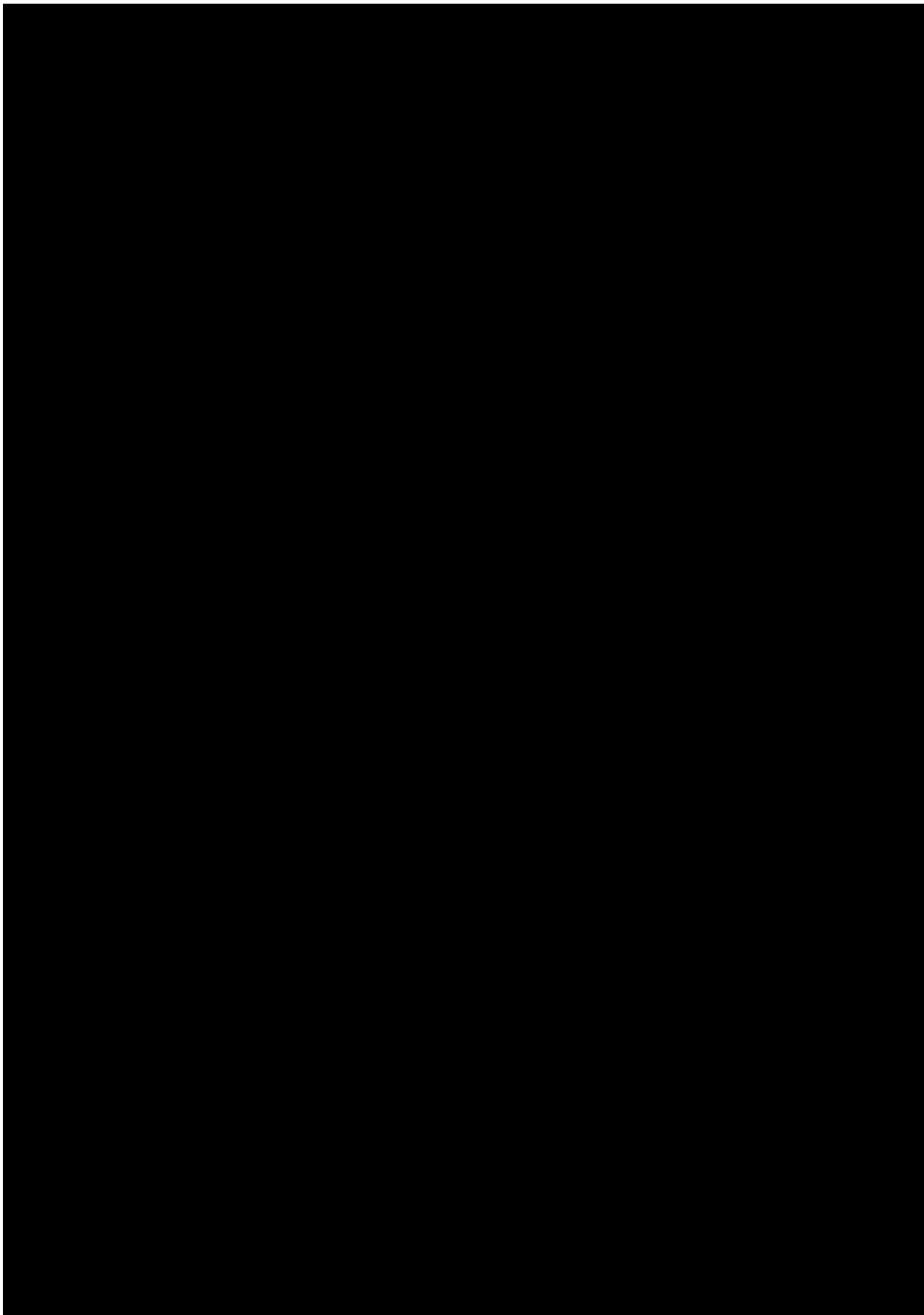


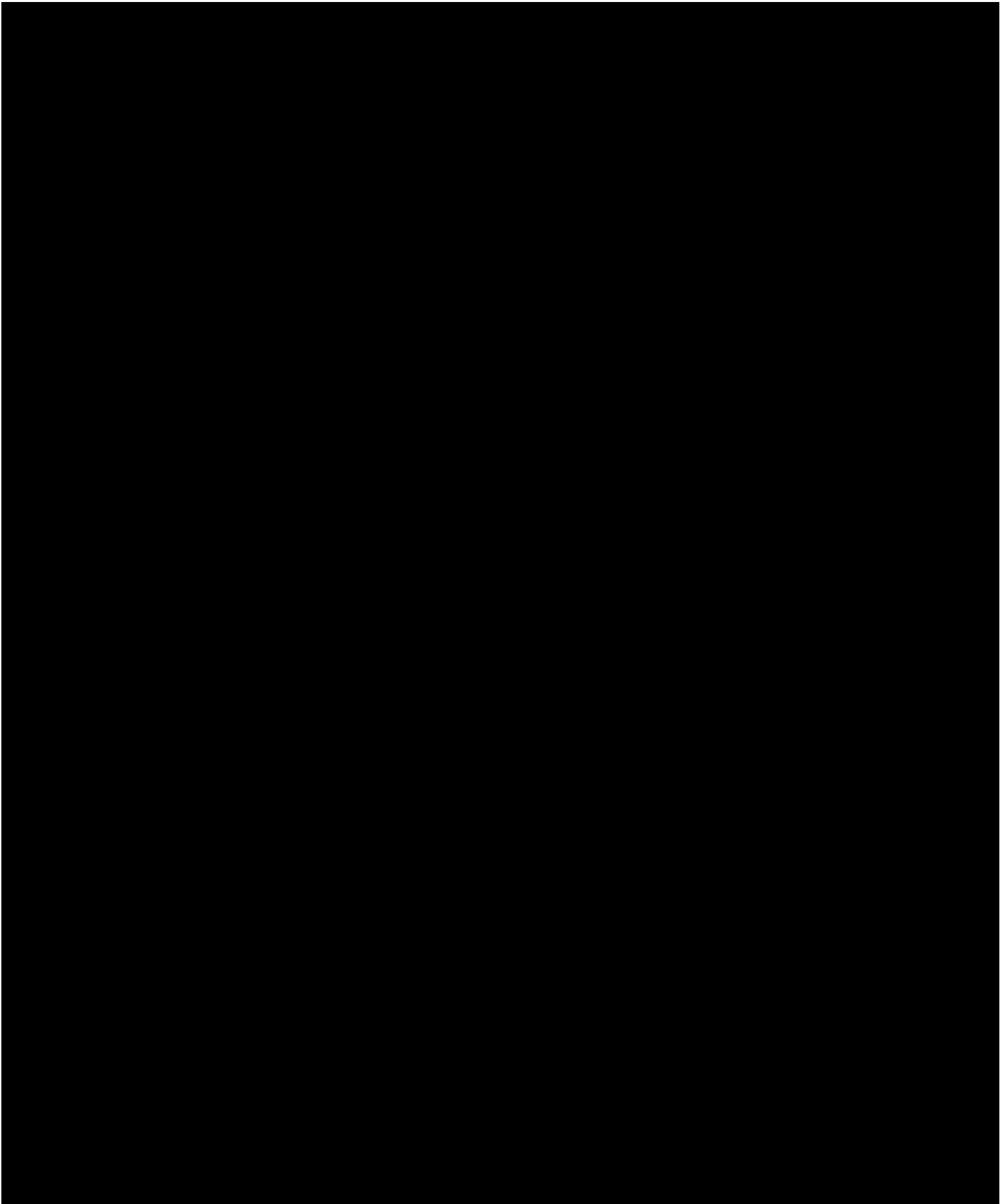


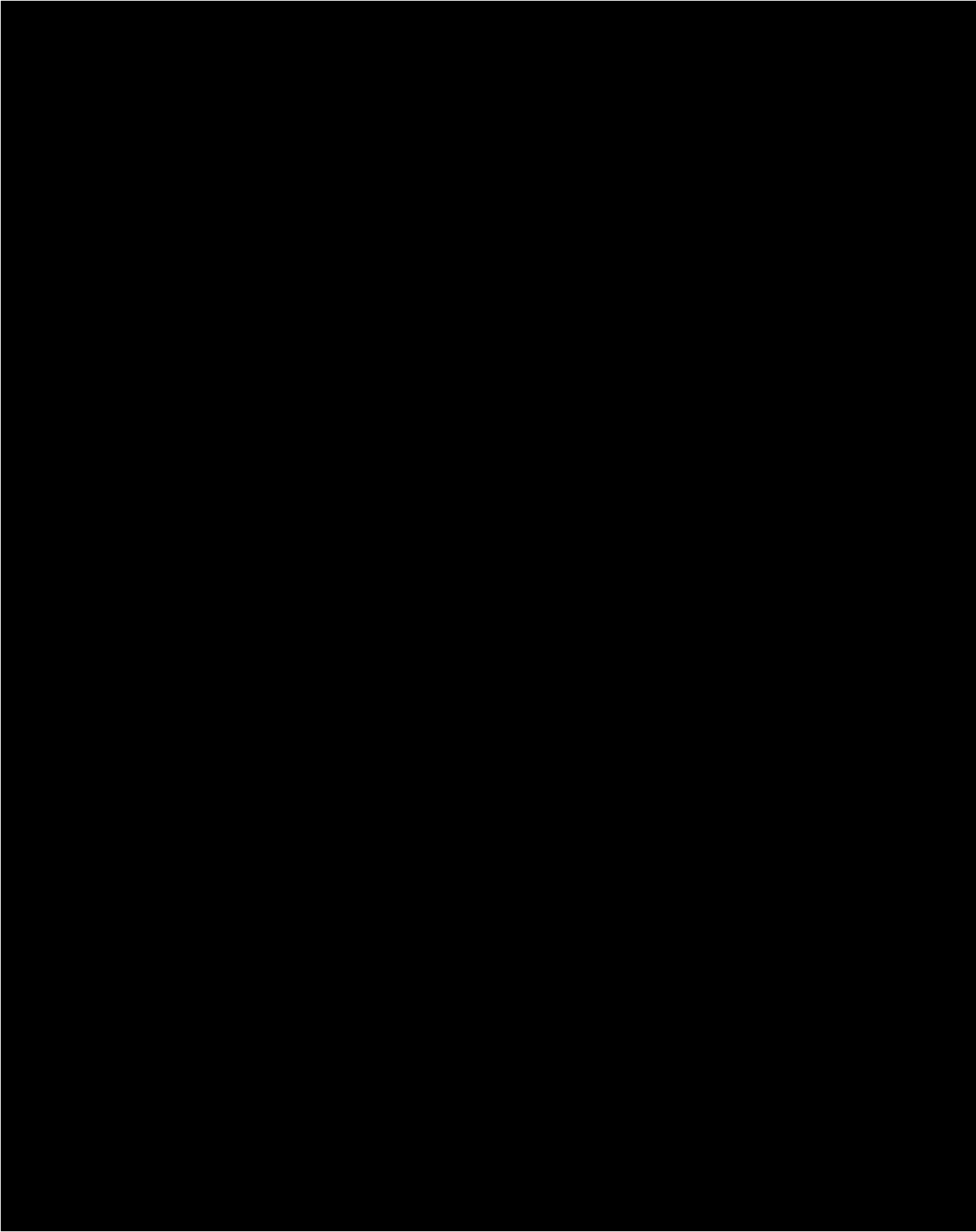


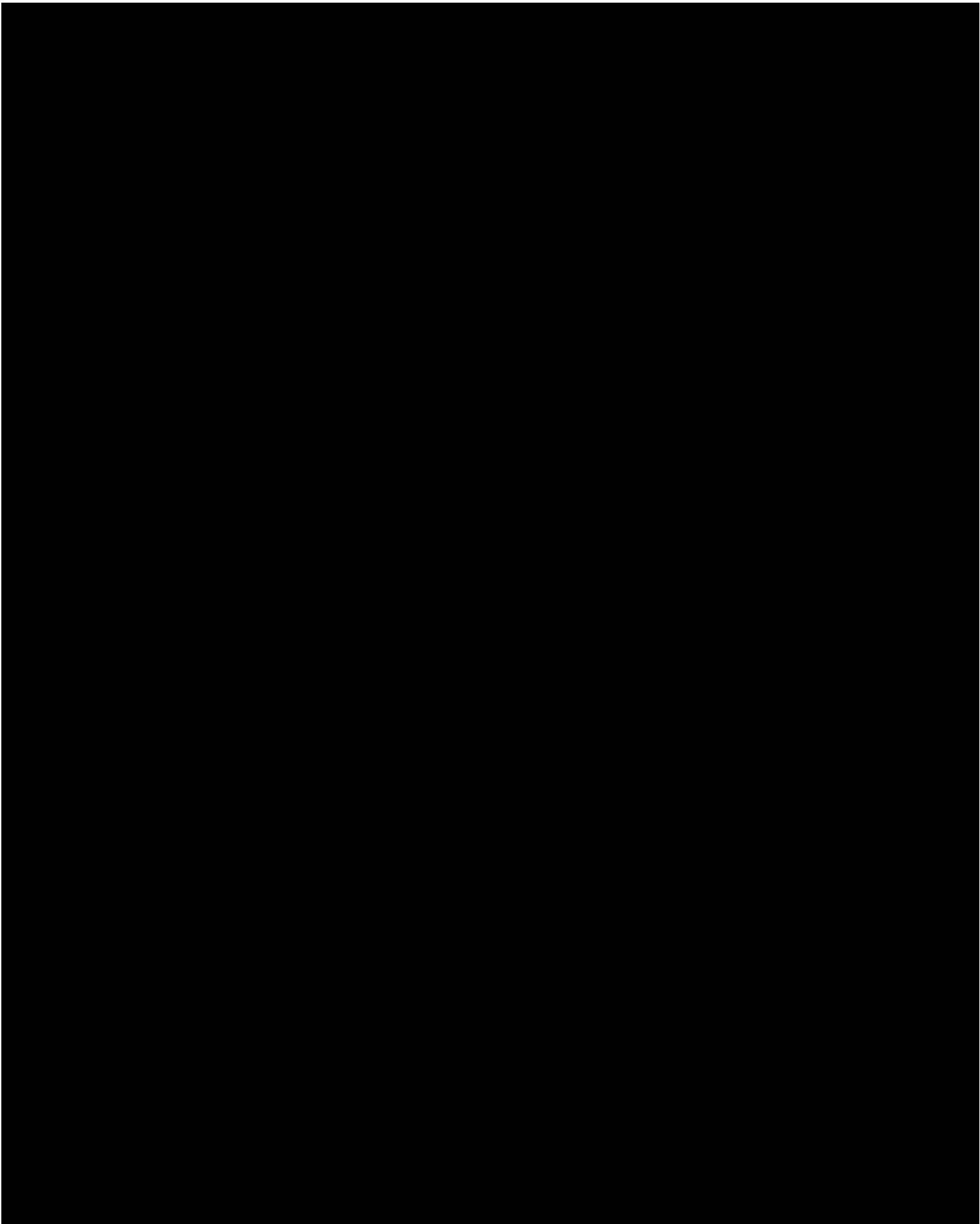






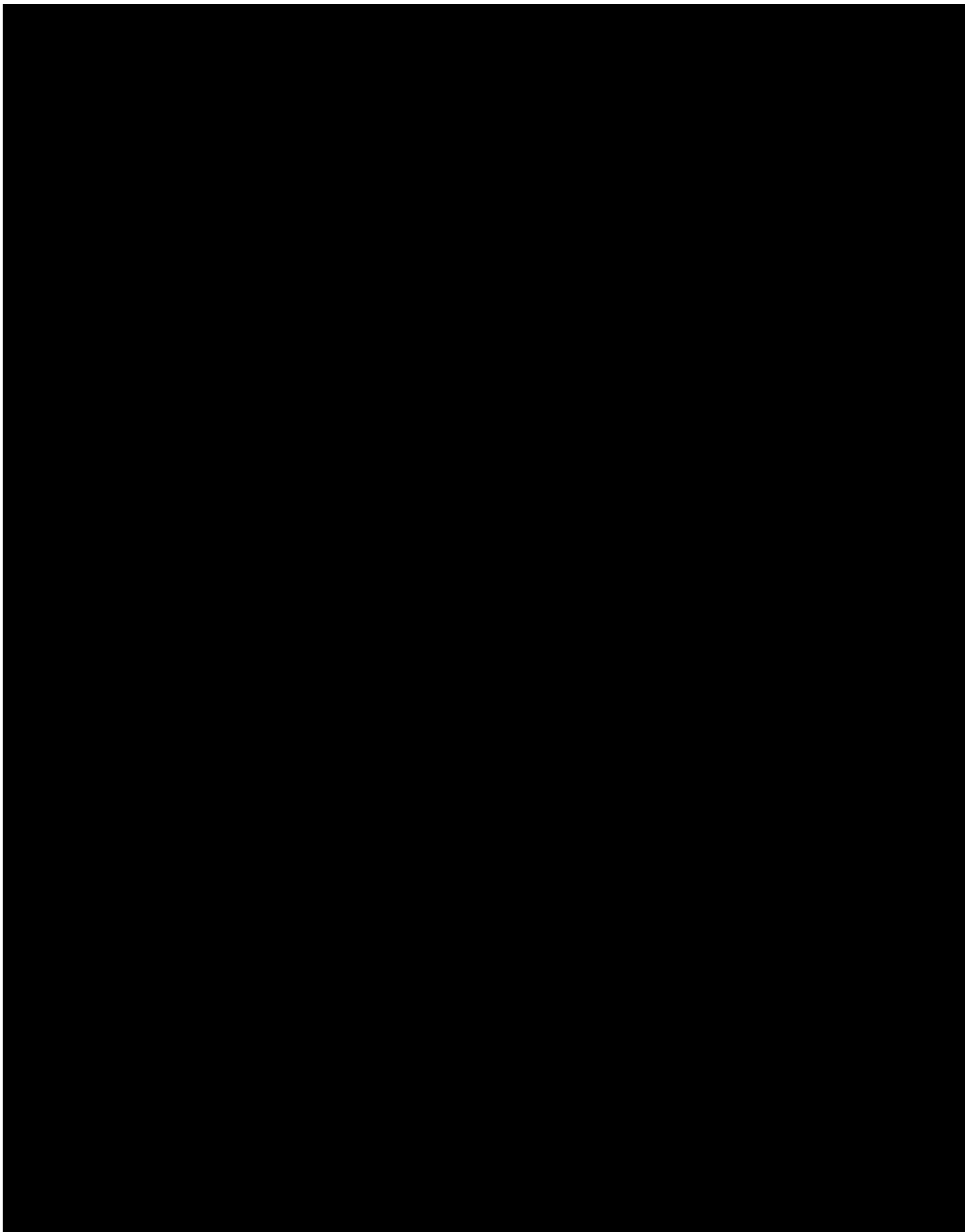


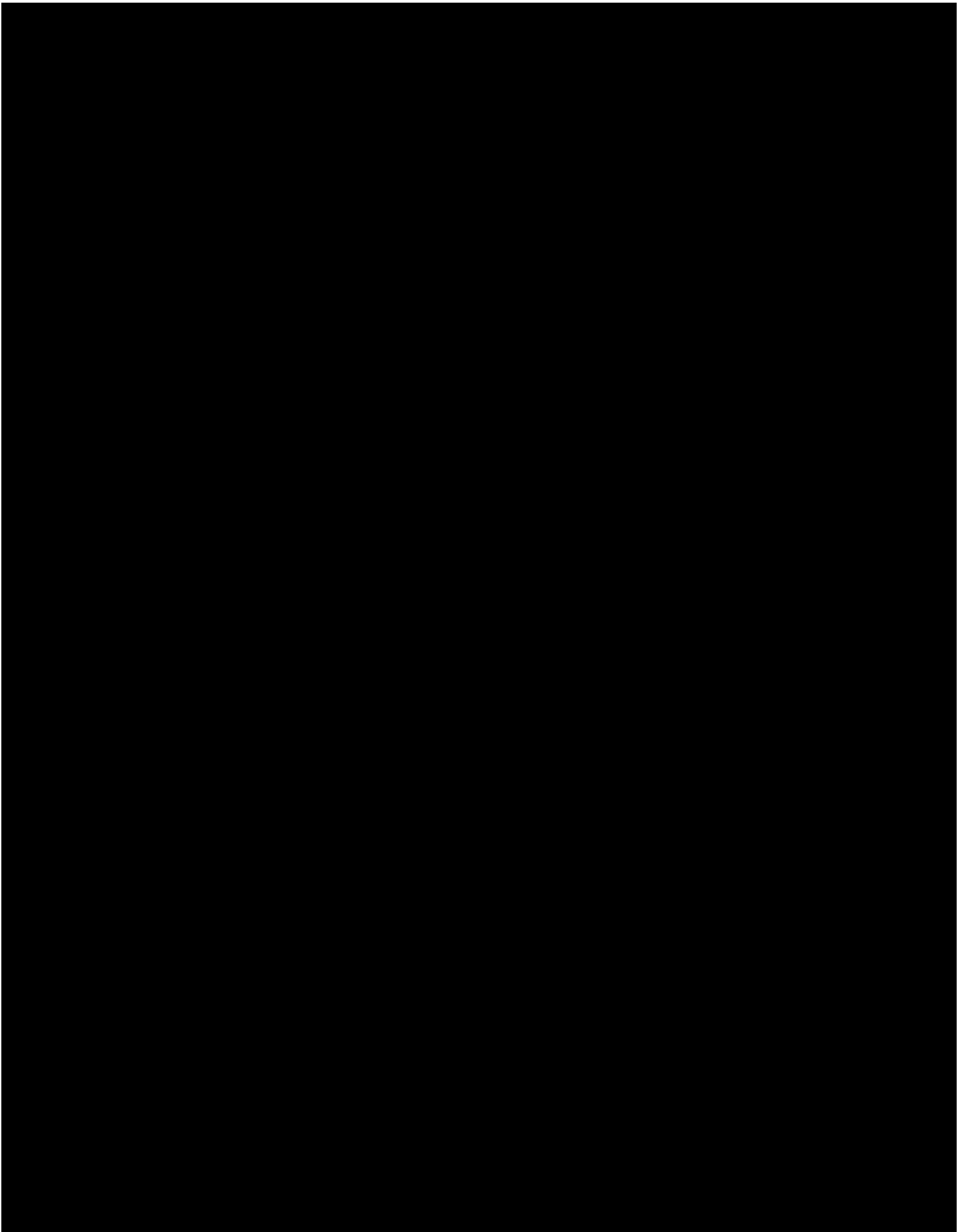


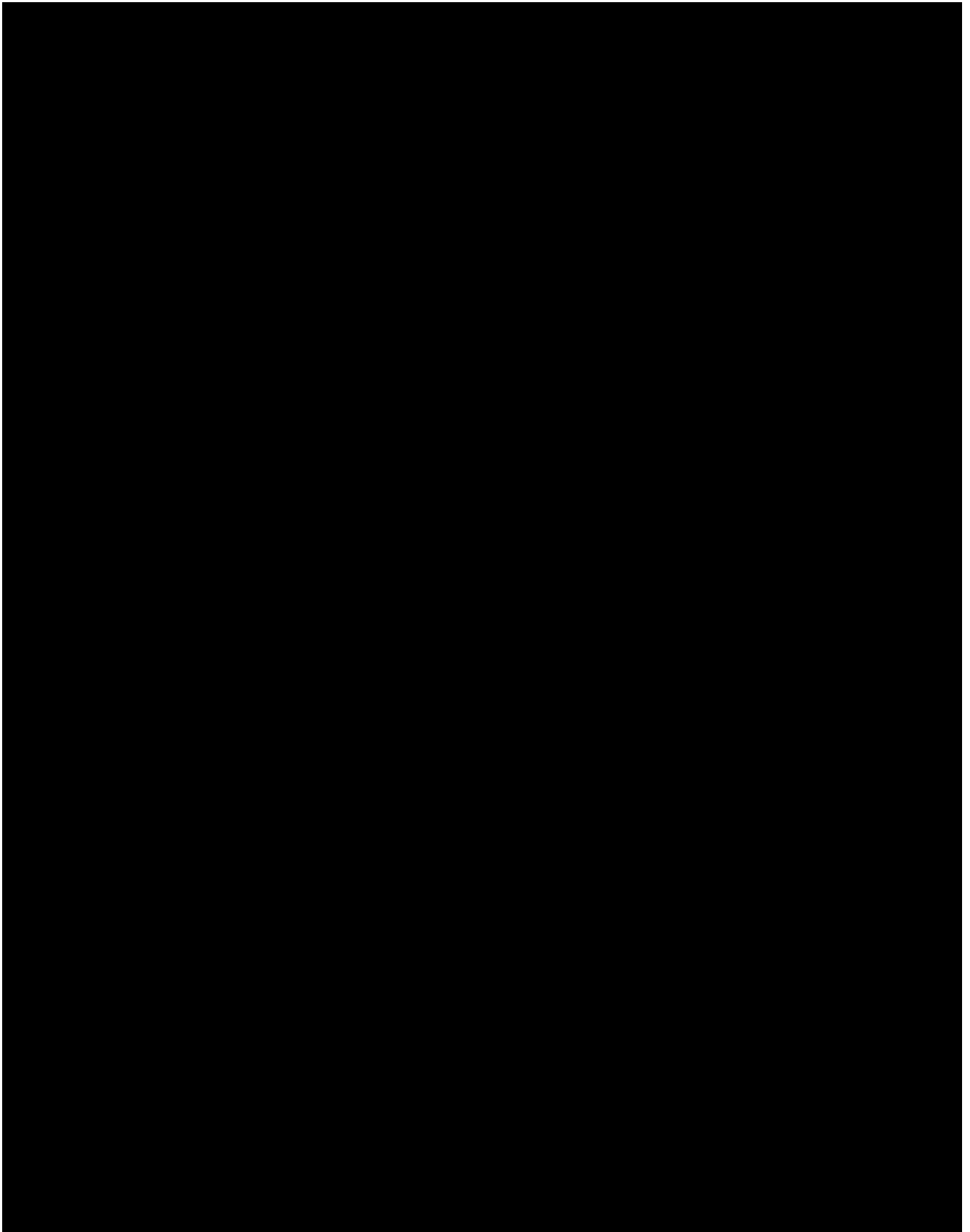


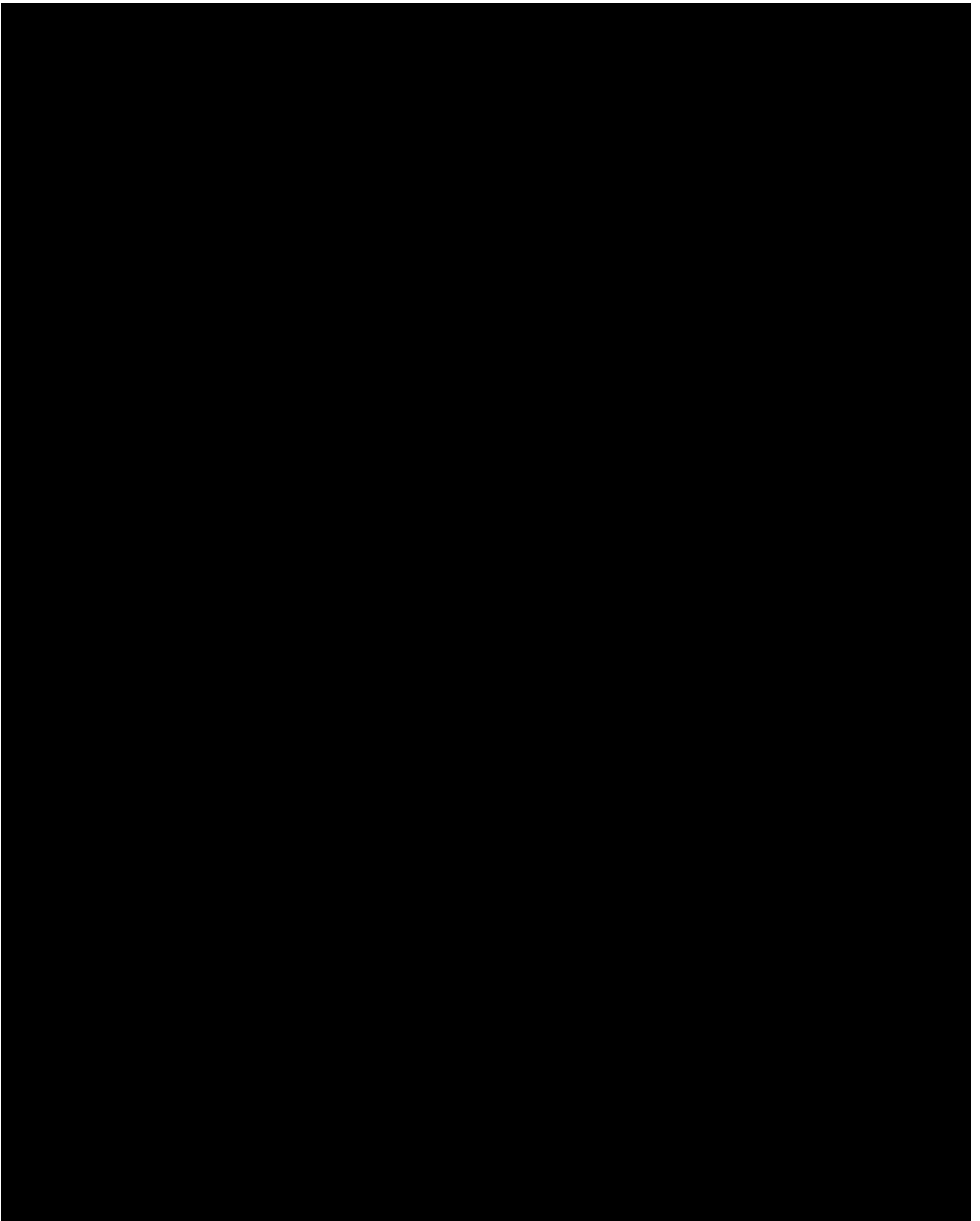


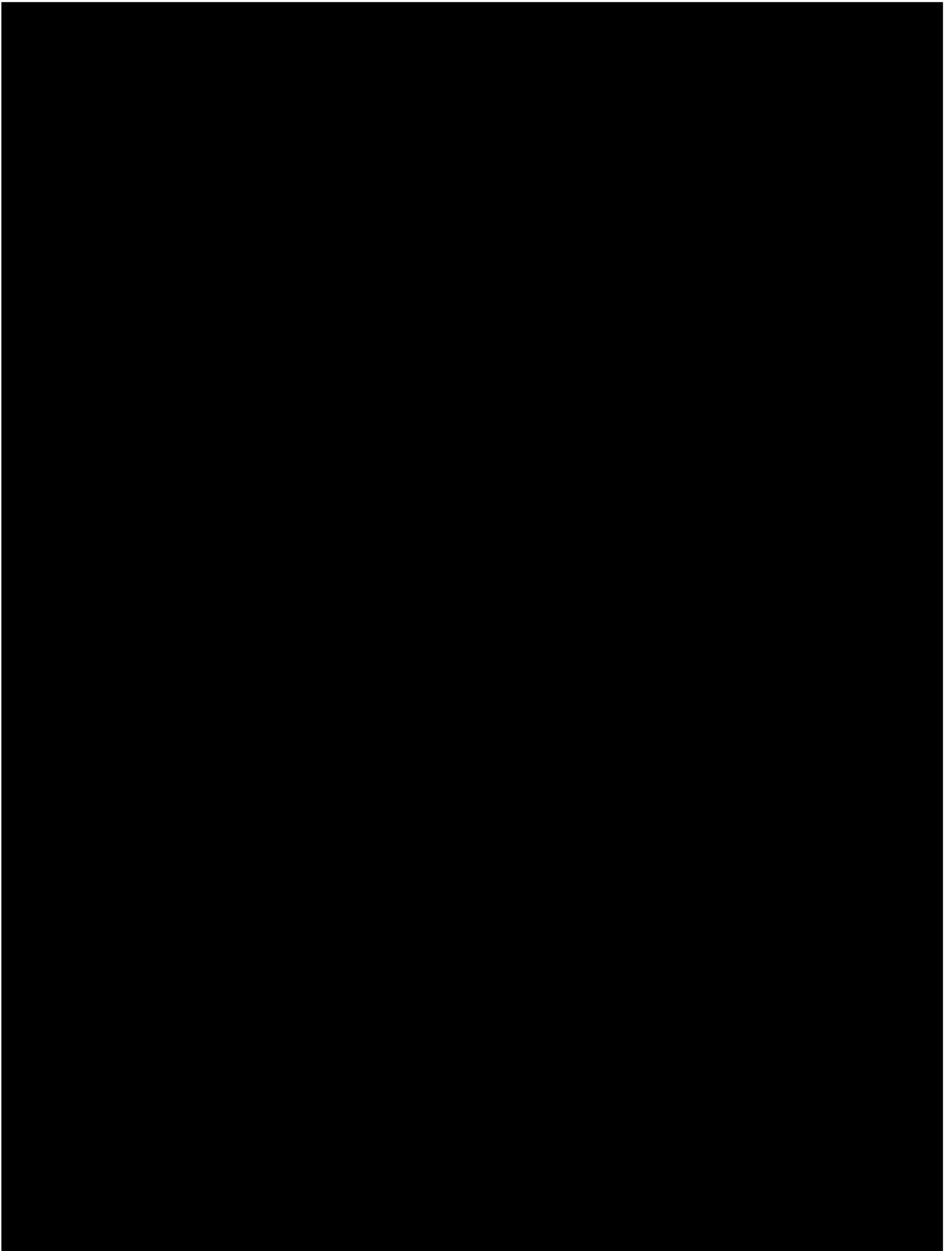


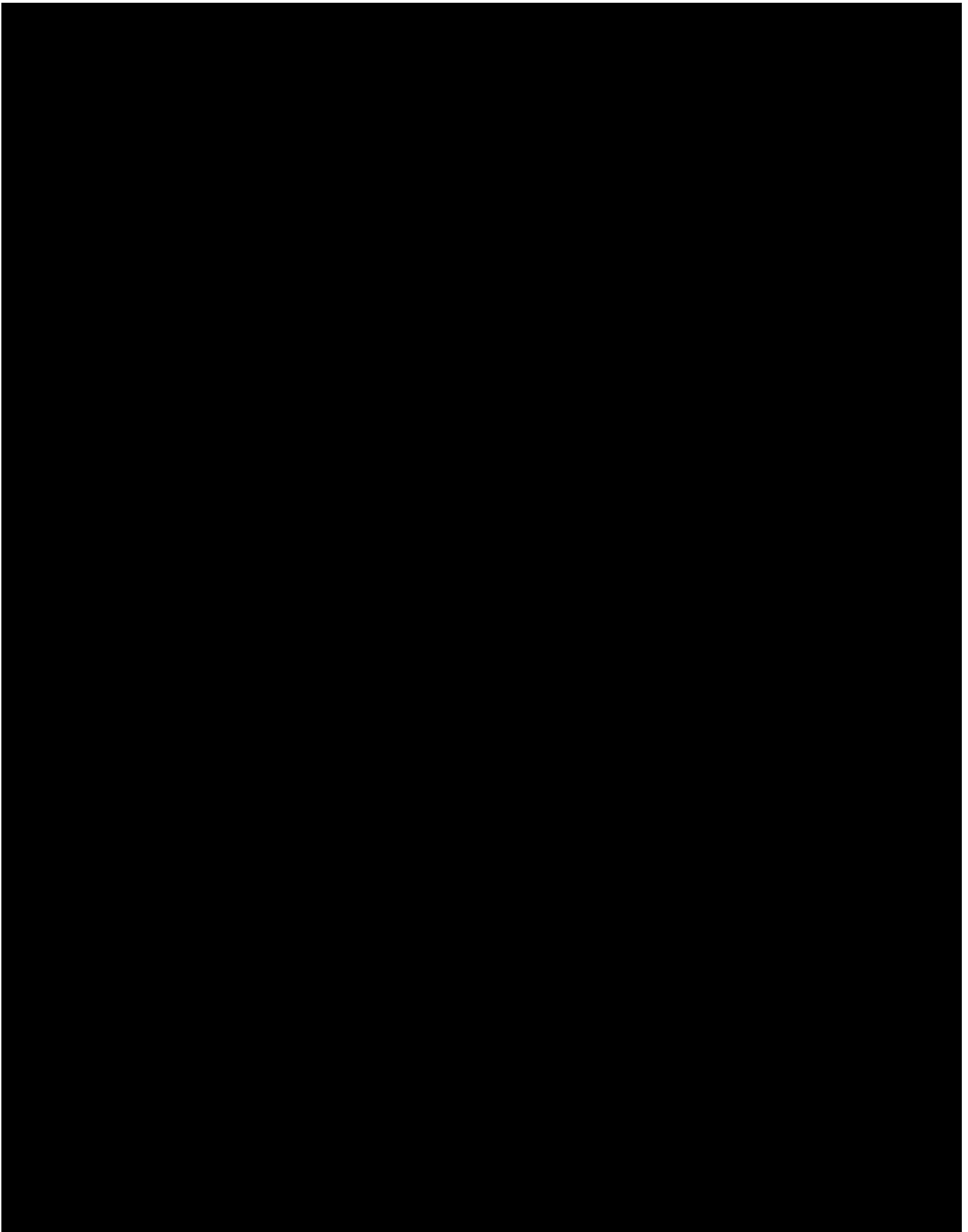


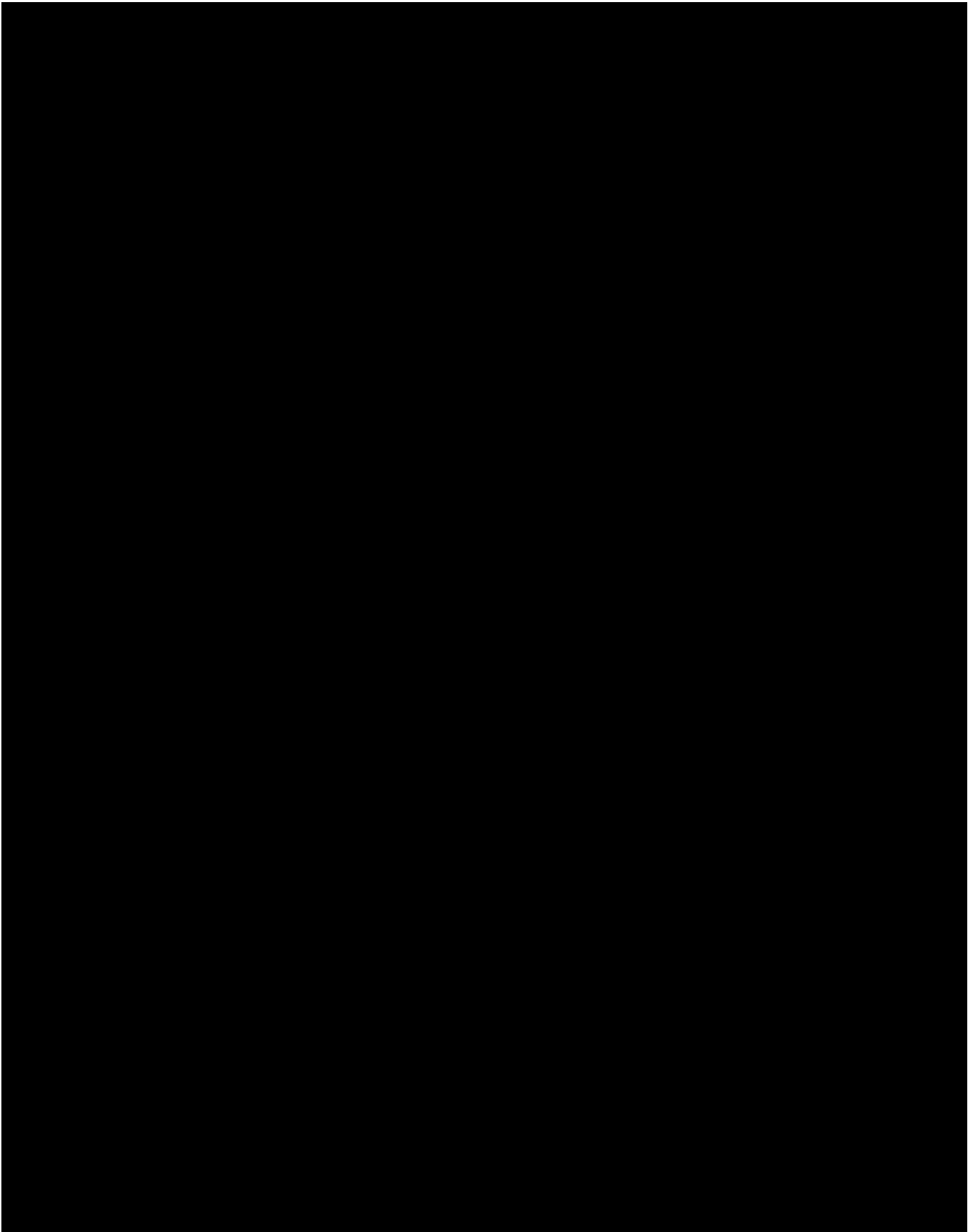




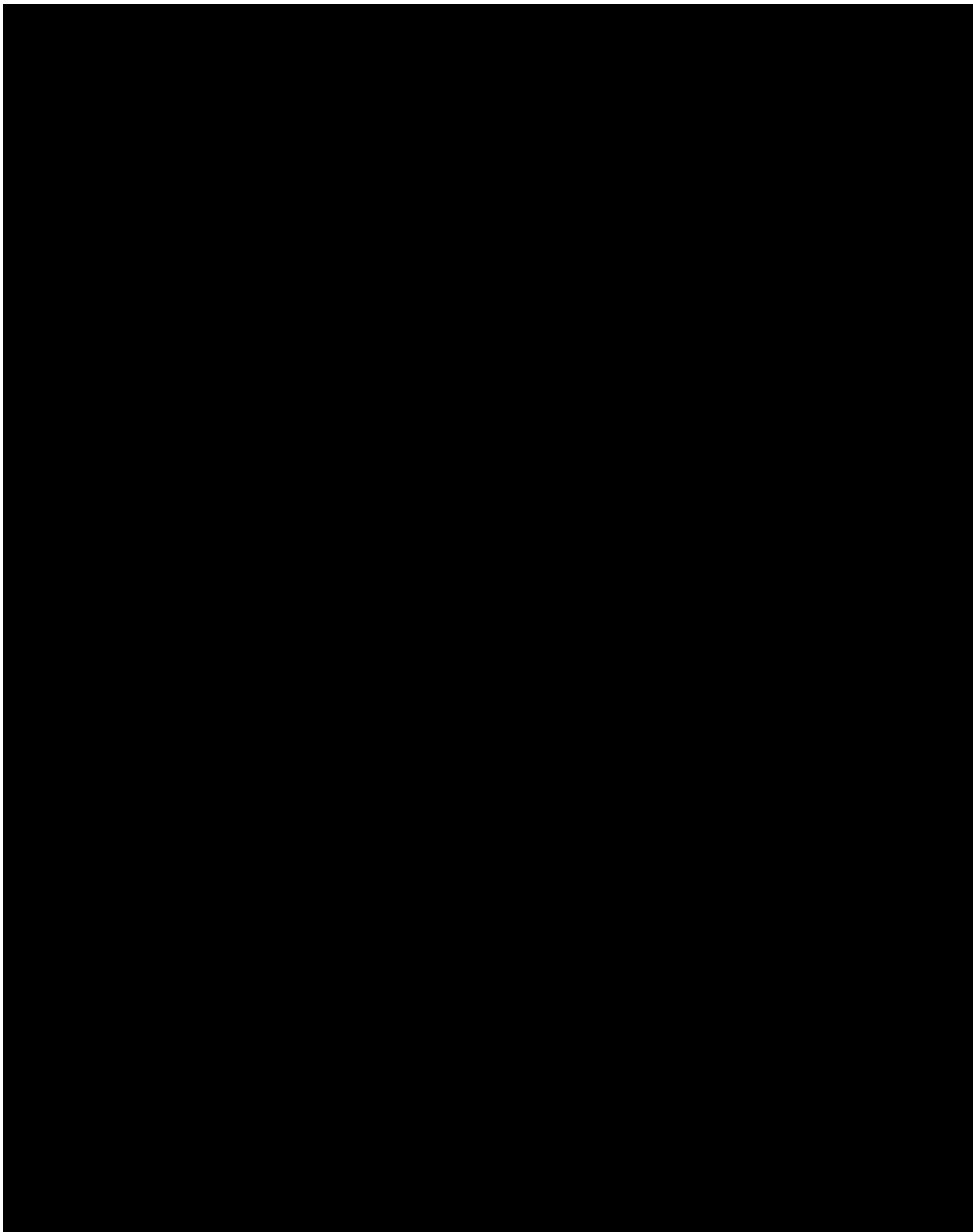


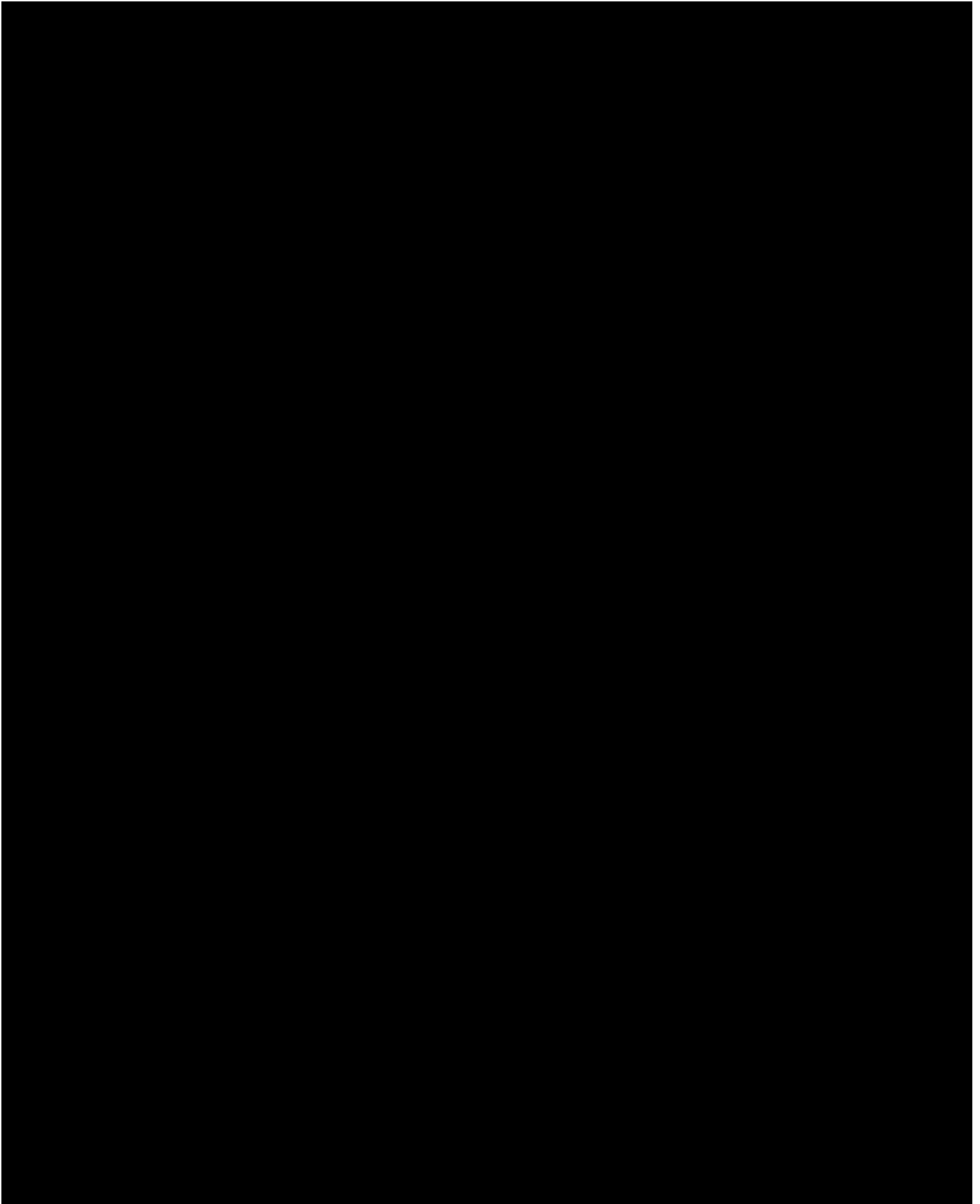


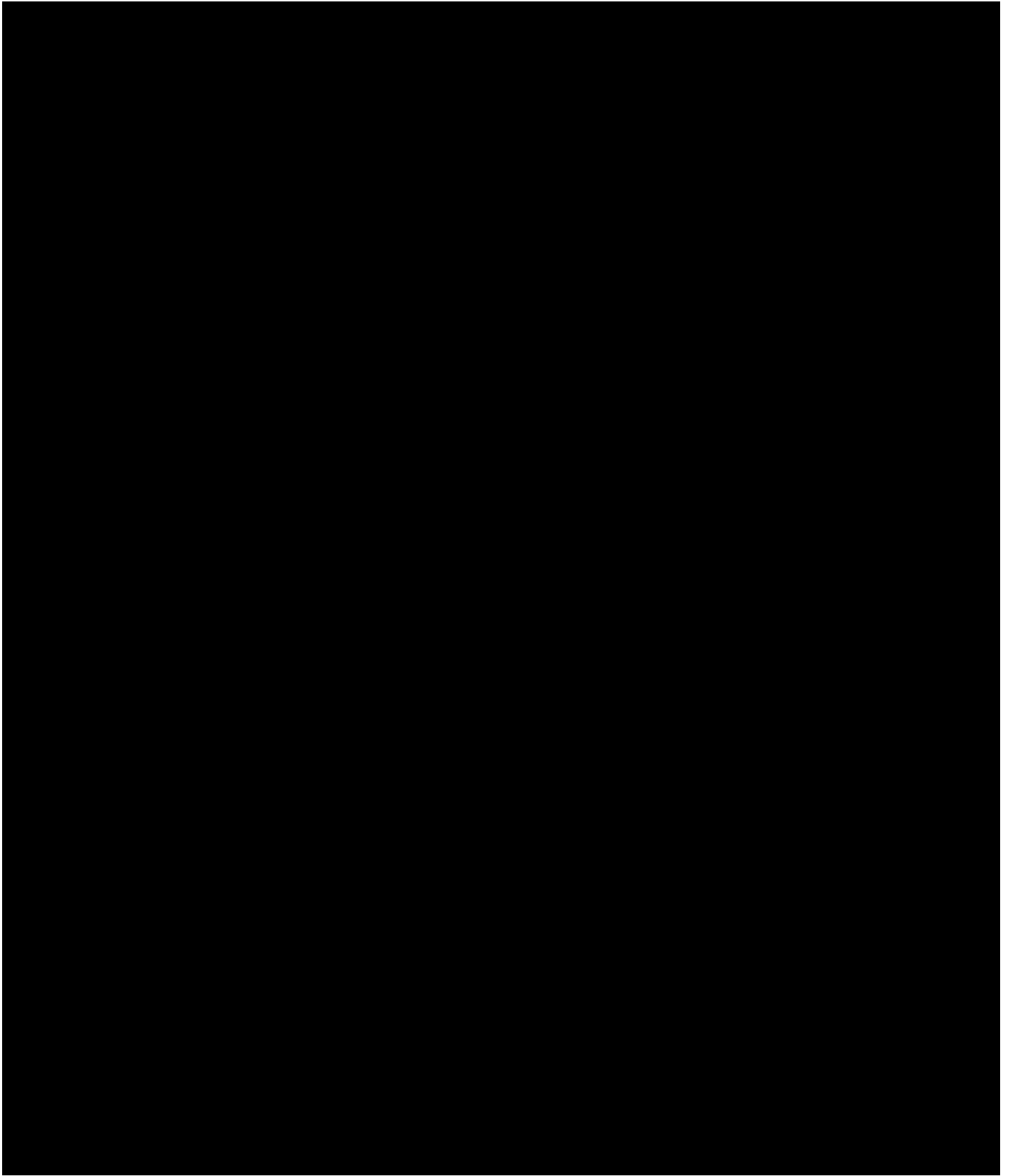


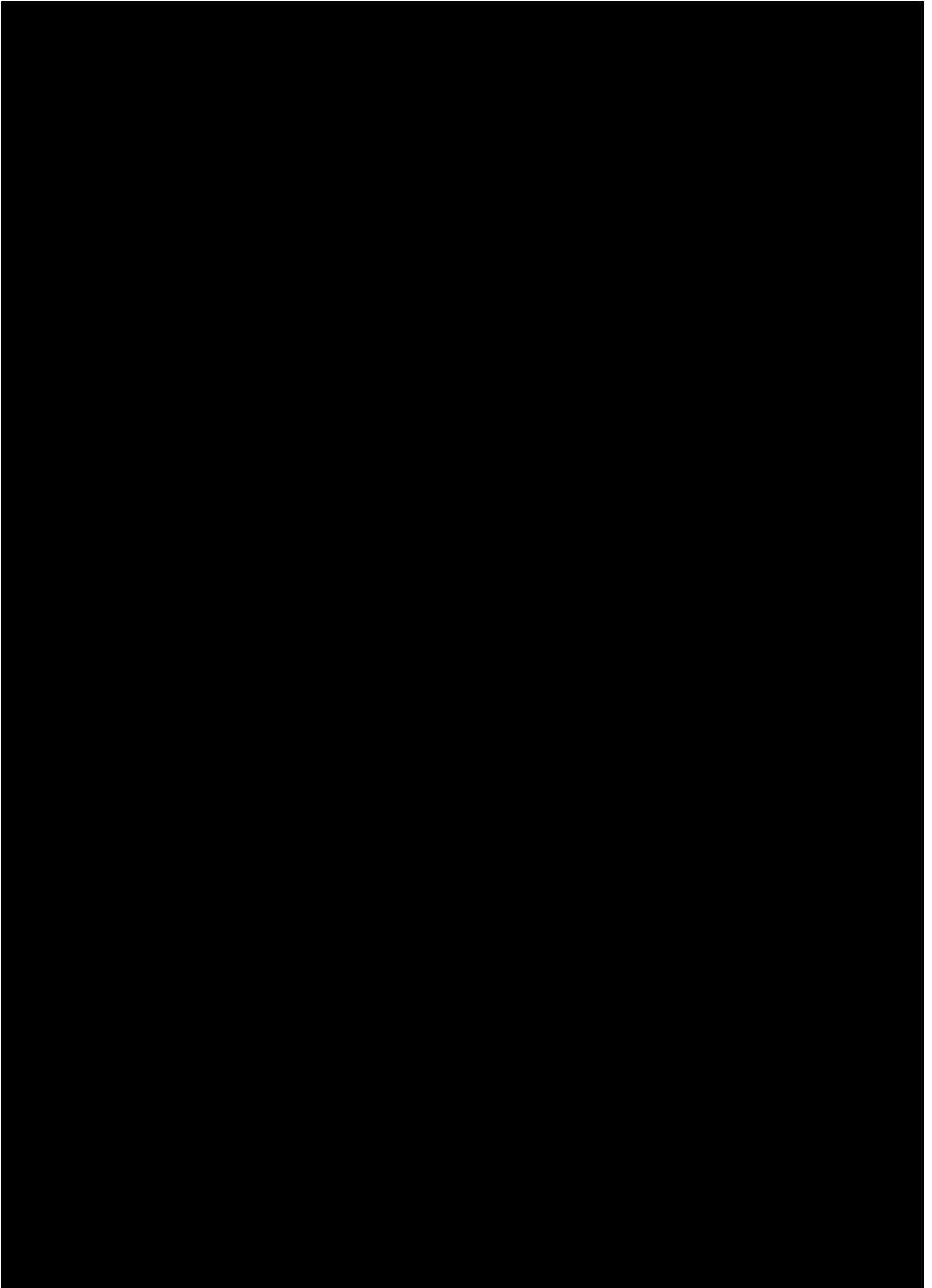


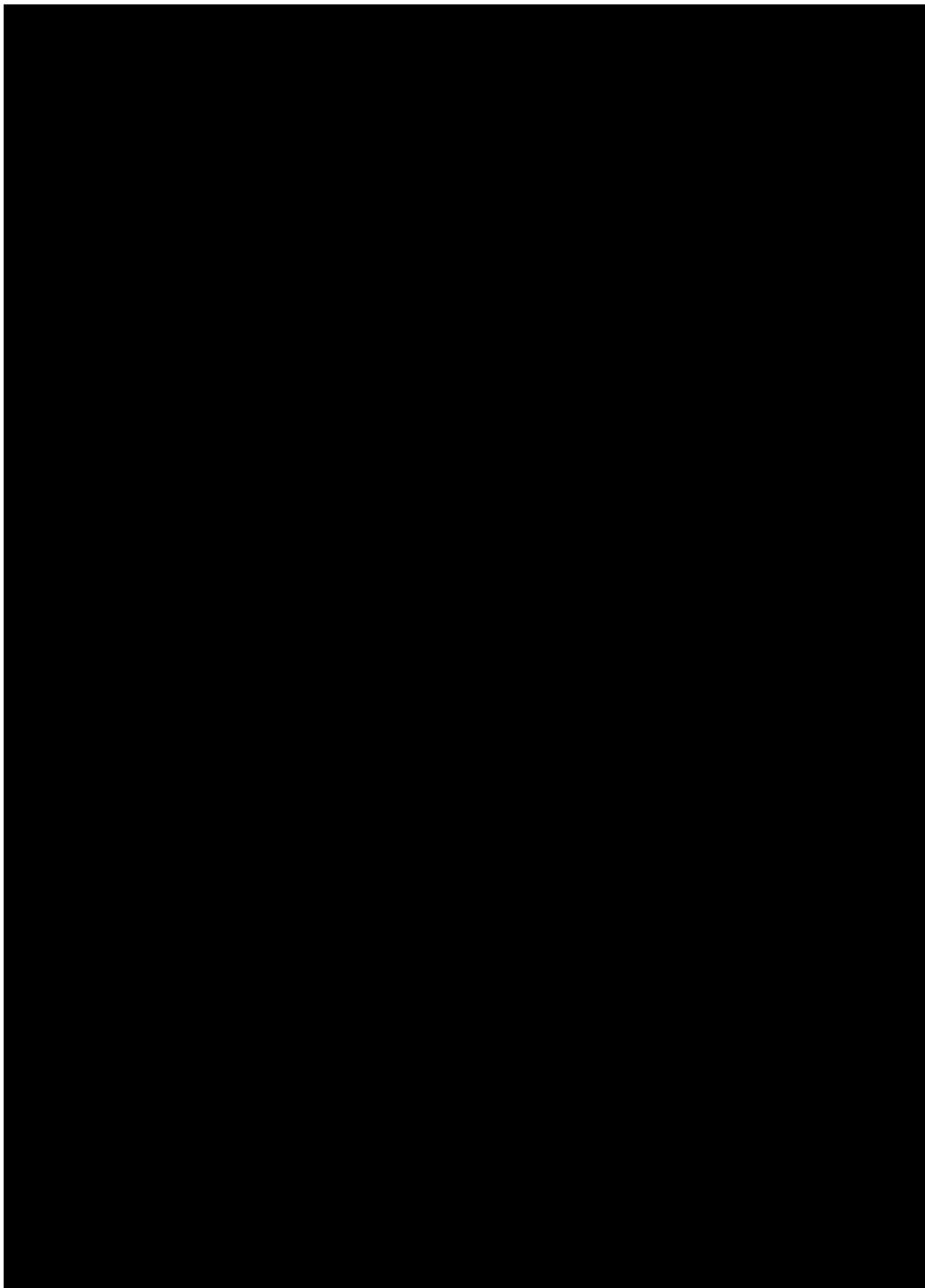


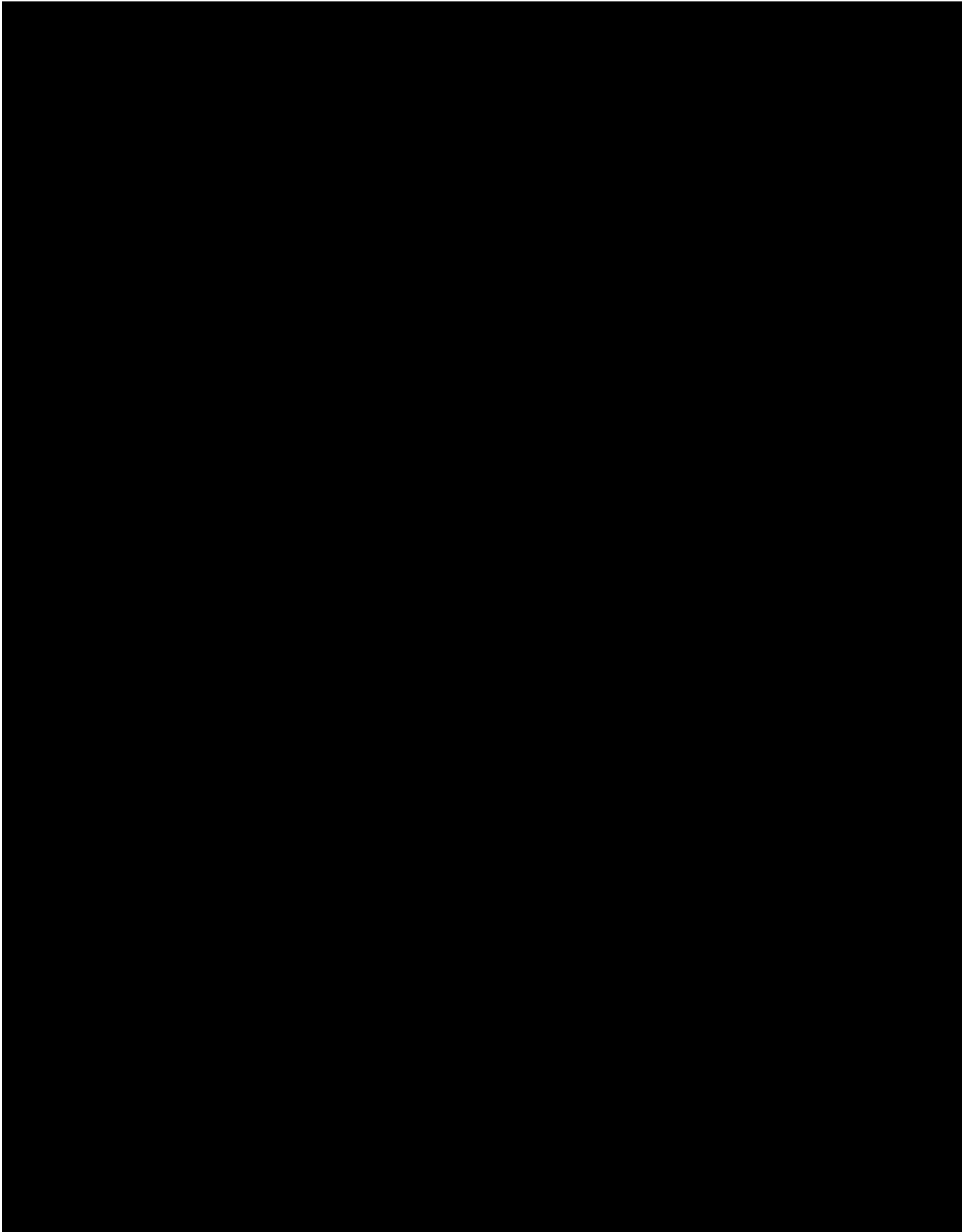


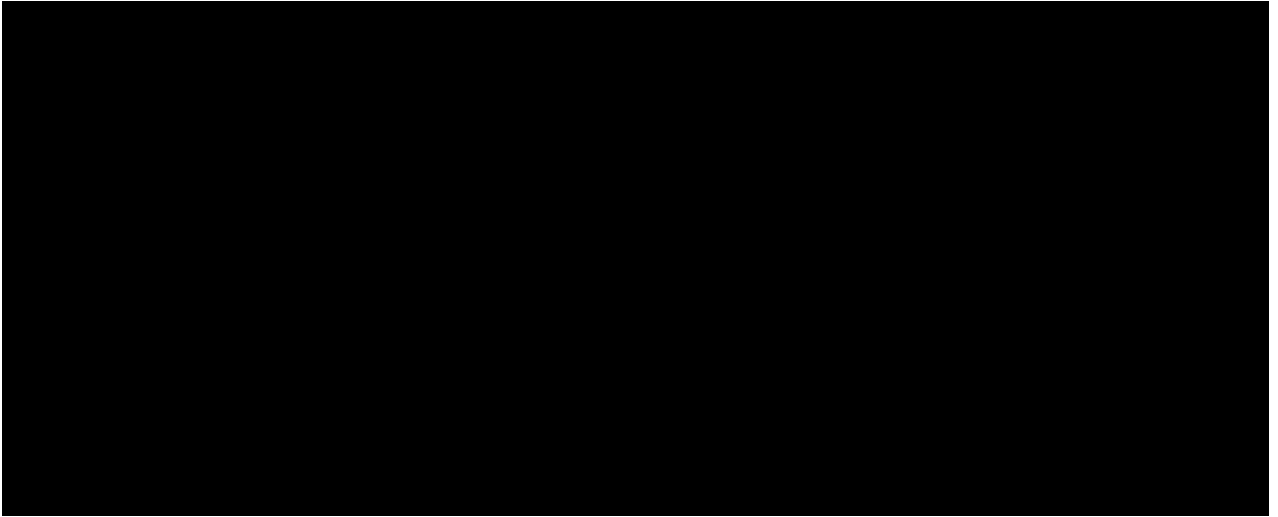


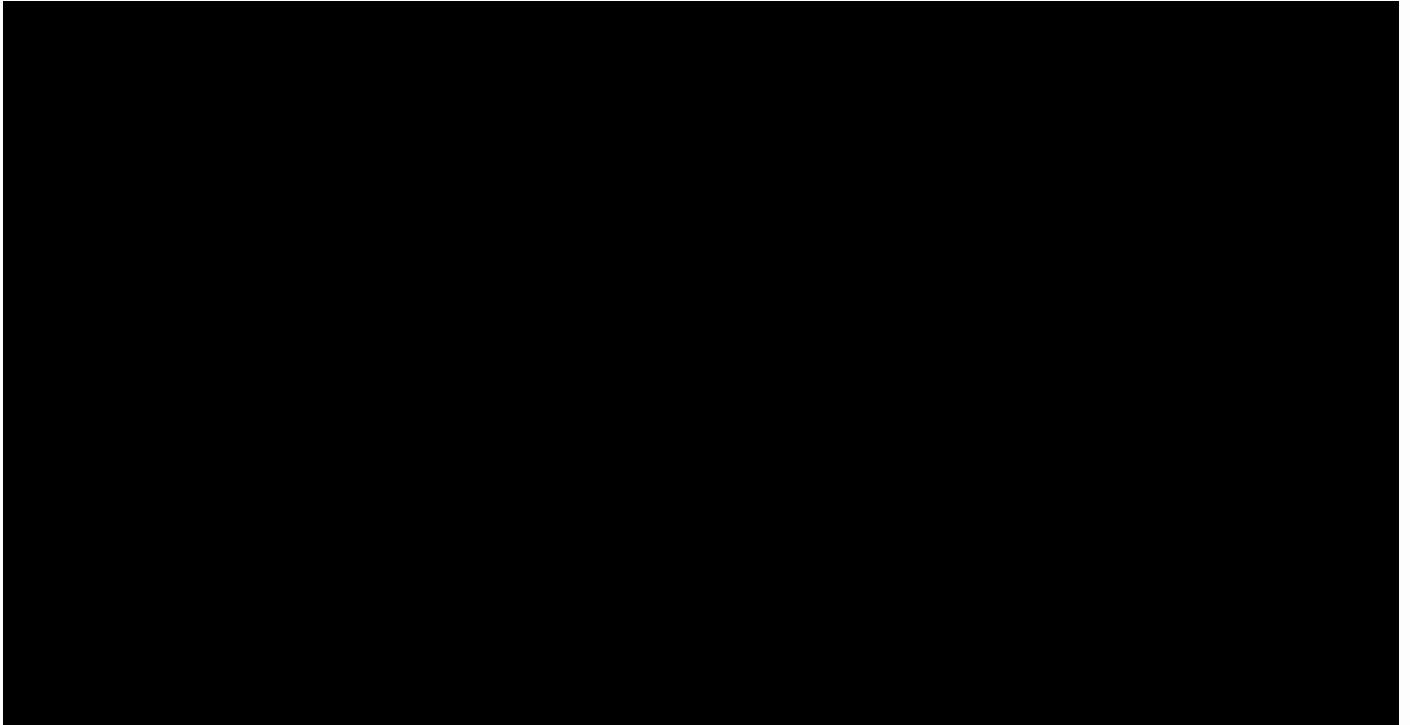














**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit H-E - REDACTED**

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF ARIZONA  
3  
4 IN RE BARD IVC FILTERS ) No. MD-15-02641-PHX-DGC  
PRODUCTS LIABILITY )  
5 LITIGATION )  
 )  
6 This document pertains to )  
 )  
7 Lisa Ann Hyde and Mark )  
Hyde, )  
8 )  
Plaintiffs, )  
9 )  
vs. )  
10 )  
C.R. Bard, et al., )  
11 )  
Defendants. )  
12 )

13 DO NOT DISCLOSE - SUBJECT TO FURTHER  
CONFIDENTIALITY REVIEW

14  
15 VIDEOTAPED DEPOSITION OF [REDACTED]  
THURSDAY, MARCH 23, 2017  
16 PALO ALTO, CALIFORNIA  
17  
18  
19  
20

21 Reported by: Shelley M. Sailor, CSR No. 10254  
22  
23

24 GOLKOW TECHNOLOGIES, INC.  
877.370.3377 ph | 917.591.5672 fax  
25 deps@golkow.com

1 MR. NORTH: No. You're just leading.

2 BY MR. LOPEZ:

3 Q. Is that what it states there, Doctor?

4 A. Yes.

5 Q. Okay. Let's go back to the fact that you  
6 have identified this as an Eclipse IVC filter. How  
7 did you identify it as an Eclipse IVC filter?

8 A. The appearance. The -- mainly the  
9 appearance of it on the x-ray.

10 Q. On the scan?

11 A. Yeah.

12 Q. In reviewing your records, you'll notice  
13 that you later describe it as a Bard G2X. Do you  
14 recall that?

15 A. Yes.

16 Q. Is that because once you were actually able  
17 to see the device, you were able to distinguish it  
18 between a G2X and an Eclipse?

19 A. It's the same filter. One of them is just  
20 another name for when they added an electro-polish  
21 on the device. But it's pretty much the same  
22 filter.

23 Q. Okay. Do you know where that filter is?

24 A. I don't.

25 Q. Were you able to distinguish that this was

1 Q. All orders and results?

2 A. Yes.

3 Q. The date -- I don't know whether that's --  
4 is that a date [REDACTED]

5 A. What was the question?

6 Q. Well, there's a date it looks like  
7 electronically signed and it says results -- let's  
8 start it says, [REDACTED] and it  
9 says completed on [REDACTED] [REDACTED]  
[REDACTED] [REDACTED]

11 A. I'm not sure what that date refers to.

12 Q. Okay. And then there it shows you as the  
13 attending physician, and you had three other of your  
14 colleagues with you at the deposition -- at the  
15 deposition -- at the surgery. Correct?

16 A. Yes.

17 Q. Okay. Now go to the next page, 55. And  
18 under Findings it says, [REDACTED]

[REDACTED] Do you see that?

20 A. Yes.

21 Q. And is that based on your experience of  
22 having dealt with that device before, that you were  
23 able to identify it as a G2X filter?

24 A. Yes.

25 MR. NORTH: Objection to the form. Asked

**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit H-F - REDACTED**



Deposition of:  
**Robert McMeeking , Ph.D.**

*July 6, 2017*

In the Matter of:  
**In Re: Bard IVC Filters Products  
Liability**

**Veritext Legal Solutions**  
1075 Peachtree St. NE , Suite 3625  
Atlanta, GA, 30309  
800.808.4958 | [calendar-atl@veritext.com](mailto:calendar-atl@veritext.com) | 770.343.9696

## In Re: Bard IVC Filters Products Liability

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1 market.

2 BY MS. DALY:

3 Q Is it your opinion that Bard failed to  
4 reduce as far as reasonably practicable the  
5 remaining risks by taking adequate protection  
6 measures?

7 A Can you repeat the question, please.

8 Q Yes.

9 Is it your opinion that Bard failed to  
10 reduce as far as reasonably practicable the  
11 remaining risks by taking adequate protection  
12 measures?

13 MR. O'CONNOR: Form and foundation.

14 THE WITNESS: In certain of the designs of  
15 the filters those risks, in my opinion, were not  
16 reduced to the extent practicable, and I would say  
17 that that applies to all of the models that we are  
18 discussing in the -- in the present case.

19 BY MS. DALY:

20 Q And which risks do you identify -- that  
21 you have an opinion that Bard failed to reduce?

22 A The risks of tilting, perforation,  
23 migration and fracture by fatigue.

24 Q Have you determined by any research or any  
25 other method that any other manufacturer of

## In Re: Bard IVC Filters Products Liability

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1 developed any bench tests.

2 Q And you just said you hadn't done any  
3 animal testing and you didn't --

4 A No.

5 Q -- have any ideas of protocols?

6 A I don't do animal testing and I --

7 Q Okay. With respect to the comment you  
8 just made about Bard should have taken certain  
9 measures sooner, we've talked about some of these  
10 before. The electropolishing issue, for example,  
11 you've testified before that you thought they  
12 should have done that earlier?

13 A I believe I said I rely on prof- --  
14 Dr. Richie in regard to the question of  
15 electropolishing the wires that are in the filters.

16 Q Okay. So with respect to an opinion that  
17 Bard could have electropolished its retrievable  
18 filters before it did so in the Eclipse, you're not  
19 going to give that opinion, you defer to  
20 Dr. Richie?

21 A Well, I --

22 MR. O'CONNOR: Form and foundation.

23 THE WITNESS: I'll defer to his opinion in  
24 terms of the wires, but a point I would like to  
25 make is that they could have switched to using tube



## In Re: Bard IVC Filters Products Liability

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1 materials sooner, and they could have made the  
2 material out of tube material which they could --  
3 which they could have electropolished at the stage  
4 of -- of making the filters from tube material  
5 rather than wires.

6 BY MS. DALY:

7 Q I'm sorry, I'm missing what that word is.  
8 What materials?

9 A Oh, so --

10 Q You said troop?

11 A Tube.

12 Q Tube materials.

13 A Tube, yeah.

14 Q Got it.

15 A T-u-b-e.

16 Q Okay. Do you know of any manufacturer  
17 that was using tube materials to make IVC filters  
18 before the time that Bard came out with the  
19 electropolished Eclipse?

20 A No.

21 Q Do you have any papers you can cite me to  
22 that that -- that one could electropolish wire  
23 adequately to have it improve any characteristic of  
24 an IVC filter before Bard did so in the Eclipse?

25 MR. O'CONNOR: Form.

## In Re: Bard IVC Filters Products Liability

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1 THE WITNESS: I've -- I've not  
2 investigated that aspect of the situation, and as I  
3 said before, I defer to Dr. Richie in regard to  
4 electropolishing wires.

5 BY MS. DALY:

6 Q Are there any other changes that you think  
7 Bard later made to its filters that it could have  
8 made earlier --

9 A Yes.

10 Q -- to -- to impact resistance to  
11 complications?

12 A Yes.

13 Q All right. And what are those?

14 A They could have developed caudal anchors  
15 sooner than they ultimately did. They could have  
16 developed penetration limiters sooner than they  
17 ultimately did. And they could have redesigned the  
18 filter configuration to try and find a better -- a  
19 better combination of -- of -- of phenomena that  
20 would improve the behavior of the filter in terms  
21 of the risks involved.

22 Q All right. So let's talk about caudal  
23 anchors and limiters. On what do you base your  
24 opinion that Bard could have added caudal anchors  
25 and limiters earlier than it did?

## In Re: Bard IVC Filters Products Liability

Page 33

1           A       Well, the -- the reason is that they  
2       eventually did put caudal anchors on the filters,  
3       and so my point is simply that they could have  
4       started to consider that possibility sooner than  
5       they -- they did, once they realized that caudal  
6       migration was contributing to tilt and tilt was  
7       contributing to other failures that the filter was  
8       experiencing.

9           Q       Okay. Do you know of any other IVC filter  
10      manufacturer who incorporated anchors or limiters  
11      earlier than Bard did?

12               MR. O'CONNOR: Form and foundation.

13               THE WITNESS: Not to my knowledge.

14      BY MS. DALY:

15           Q       Okay. Do you know any -- do you know in  
16      any in-depth way what the process was internally in  
17      Bard to develop these anchors and limiters?

18               MR. O'CONNOR: Form.

19               THE WITNESS: I've read some of the  
20      documents that describe activities that were  
21      involved, but I -- I wouldn't say that I know in  
22      detail what the processes were that were involved  
23      in developing those caudal anchors.

24      BY MS. DALY:

25           Q       Do you know -- do you know of design

## In Re: Bard IVC Filters Products Liability

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1 efforts that Bard made to add these anchors and  
2 limiters that were unsuccessful initially and more  
3 changes had to be made?

4 MR. O'CONNOR: Form.

5 THE WITNESS: I do know that some of the  
6 designs of the caudal anchors that they  
7 investigated did not work as well as others.

8 BY MS. DALY:

9 Q The other thing you talked about was that  
10 Bard could have redesigned the configuration of its  
11 filters. It was a little vague to me. What do you  
12 mean by that?

13 A Well, I mean the -- the shape of the  
14 limbs, the dimension of the limbs, in other words  
15 their -- their diameter, they could have considered  
16 different numbers of limbs, they could even have  
17 considered moving to a different material. So  
18 there's a fairly large number of design choices  
19 that could have been considered, and they could  
20 well have come up with a combination of features in  
21 the design that gave them a better combination  
22 of -- of phenomena in terms of how the filter  
23 behaved.

24 Q Do you know -- are you aware of any steps  
25 that Bard took along the way from Recovery to

## In Re: Bard IVC Filters Products Liability

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1 BY MS. DALY:

2 Q You talk about the changes to the G2X cap,  
3 and I want to know what your opinion is on the  
4 chamfer design in the G2X compared to the G2.

5 MR. O'CONNOR: You can refer to your  
6 report, too, it's in there.

7 BY MS. DALY:

8 Q Sure.

9 A In my opinion, the chamfer was changed  
10 very little in going from the G2 to the G2X, and  
11 the reason is that although the cap was bead  
12 blasted, the chamfer area was masked during the  
13 bead blasting and as a consequence of that, the  
14 bead blasting would not have broken the sharp  
15 edges, which are the -- the problem that is  
16 associated with the chamfer. And this is contrary  
17 to Dr. Fasching's claim that the bead blasting  
18 would have softened that particular sharp edge.

19 The next point is that after the bead  
20 blasting, there was a process of tumbling the cap  
21 in a bed of ceramic particles, and that would have  
22 removed some material by a process of pol- --  
23 essentially polishing, mechanical polishing, but in  
24 my assessment it would not have removed a great  
25 deal of material and, therefore, would not have

## In Re: Bard IVC Filters Products Liability

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1 changed the shape of the chamfer very much.

2 And as information that's consistent with  
3 that, we can look at Figure -- Figure 187 in  
4 Dr. Fasching's report, which the report dated May  
5 11 of 2017, where it can be seen that there are two  
6 rounded edges at the bottom of the cap; one of them  
7 is very gradual, which is the one on the outside,  
8 and my assessment is that that edge was broken by  
9 the bead blasting; whereas the one on the inside of  
10 the cap adjacent to the limb you can see is much  
11 sharper in the sense that the radius of curvature  
12 is much smaller than the other curved surface.

13 And I did an estimate of the radius of  
14 curvature and I found that the radius of curvature  
15 for that chamfer is about 20 microns. Now, I would  
16 defer to those who measure the -- the radius of  
17 curvature directly in images on the electron  
18 microscope and so on, so I'm not going to say this  
19 is a definitive measure of the radius of curvature,  
20 but it leaves me with the impression that the  
21 radius of curvature is about 20 microns. And the  
22 radius of curvature that was measured by  
23 Dr. Fasching on a Recovery filter quite some time  
24 ago was 15 microns.

25 And so it's my inference that there was

## In Re: Bard IVC Filters Products Liability

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1 not a big change to the radius of curvature of the  
2 chamfer in the processes that were used in the  
3 manufacture of the G2X. And that, therefore, the  
4 strain concentration which would be associated with  
5 that chamfer was not reduced significantly,  
6 although if some material was removed, it would  
7 have reduced the strain concentration to some  
8 extent.

9 Q Okay. So, first of all, let me start with  
10 that last thing first. You have not done any  
11 specific modeling or FEA to determine what the  
12 change in chamfer that you're willing to say  
13 occurred to this 20 millimeters -- microns,  
14 would -- what that impact would be on fracture  
15 resistance? You have not done any of that work  
16 specifically?

17 A Well, I've -- I've considered the  
18 difference between a radius of curvature of 5  
19 microns and one in which, if you like, the radius  
20 of curvature is very large, but in between -- which  
21 spans the range from a radius of curvature of 5  
22 microns to ones which are much larger. But other  
23 than that, I've not done a specific calculation.

24 But I should point out that the reduction  
25 is proportional to the degree of change of the

## In Re: Bard IVC Filters Products Liability

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1 severe stiffness constraint on whether the relative  
2 motion of the arms and the legs can be accommodated  
3 as the filter, if you like, tries to stretch. So  
4 that -- that's a possibility.

5 Q Do you have any case that you can point to  
6 that you have worked on where there was imaging  
7 evidence of perforation, tilt or migration that  
8 occurred before a leg fracture?

9 A I haven't looked into that.

10 MR. O'CONNOR: Belated objection to the  
11 form of the question.

12 BY MS. DALY:

13 Q Have you done any work to determine what  
14 modifications Bard could have made to the legs  
15 themselves to improve on those legs' contribution,  
16 if any, to tilt, perforation, fracture or  
17 migration?

18 A No, I haven't looked into that.

19 Q We've talked a little bit about the  
20 anchors and limiters present on the Meridian. Is  
21 it your opinion that those are reasonable  
22 modifications by Bard to -- to improve resistance  
23 to migration, tilt and perforation?

24 A It's a reasonable concept for how the tilt  
25 and migration behavior can become -- can be



## In Re: Bard IVC Filters Products Liability

Page 130

1 limited.

2 Q Would -- do you have an opinion whether  
3 those anchors or limiters on the Meridian would add  
4 fracture resistance to that filter?

5 A I have no opinion on that.

6 Q Same questions with Denali, do you think  
7 that the limiters that the Denali has will act to  
8 improve resistance to migration, tilt, perforation  
9 and fracture?

10 MR. O'CONNOR: Form.

11 THE WITNESS: It's -- it is reasonable to  
12 expect that there will be some effect on -- on tilt  
13 and migration and that those would have possible  
14 knock-on consequences to perforation and fracture.  
15 And so I'd like to revise my answer about the  
16 Meridian in the same way, that the caudal anchors,  
17 to the extent they limit tilt and migration, they  
18 could have beneficial effects on perforation and  
19 fracture.

20 BY MS. DALY:

21 Q Okay. What modifications to the G2 filter  
22 assisted in resistance to cephalic migration? Do  
23 you have an opinion on that?

24 MR. O'CONNOR: Form.

25 THE WITNESS: I'm not aware of any changes

## In Re: Bard IVC Filters Products Liability

Page 203

1 but does not change its orientation relative to the  
2 vena cava wall, then the stiffness will be four  
3 times, which means that the force will -- that you  
4 apply will be four times that which you got when  
5 you did not constrain the rotation.

6 Q Okay. And that stiffness in the petal  
7 area may make folding that back down, once it's in  
8 the patient to put it in a sheath for retrieval,  
9 more difficult?

10 A It would mean --

11 MR. O'CONNOR: Form.

12 THE WITNESS: It would mean --

13 MR. O'CONNOR: Foundation.

14 THE WITNESS: It would mean that you have  
15 to pull on the filter with a bigger force relative  
16 to the Recovery catheter to put into that Recovery  
17 catheter.

18 BY MS. DALY:

19 Q And what that might translate into insofar  
20 as patient injury, you do -- you have not done an  
21 analysis of that?

22 A I have not done an analysis of that.

23 Q All right. Now, this is what I wrote down  
24 about your conclusions from the SNF report, and I  
25 want to talk about these separately and tell me if

## In Re: Bard IVC Filters Products Liability

Page 221

1 that?

2 A No.

3 MR. O'CONNOR: Form.

4 BY MS. DALY:

5 Q Nor did you do it with the Denali  
6 laser cut from a nitinol tube that also has  
7 anchors?

8 MR. O'CONNOR: Form.

9 THE WITNESS: I didn't do any of those  
10 analyses because it's my assessment that those  
11 changes did not make a significant difference  
12 to the -- to the filters in terms of reducing  
13 the danger that they present because of their  
14 failures.

15 BY MS. DALY:

16 Q Are you giving the opinion that the Simon  
17 nitinol is an alternative safer product than the  
18 Bard retrievable products?

19 MR. O'CONNOR: Form.

20 THE WITNESS: I'm offering the opinion  
21 that in the setting of permanent use of a filter,  
22 which the Recovery and the G2 and its successors  
23 can -- can be used as, that the Simon nitinol is a  
24 safer alternative.

25 BY MS. DALY:

## In Re: Bard IVC Filters Products Liability

Page 308

1 Q And when you talk about worst-case  
2 scenario, is that a standard that engineers are  
3 required to follow?

4 A Yes, in dealing with this kind of problem,  
5 engineers are expected and required to identify the  
6 worst-case conditions and then take that into  
7 consideration when assessing the performance of  
8 their design and the consequences of -- of the  
9 design.

10 Q Now I want to -- I want to move around a  
11 little bit. Well, let me ask you about  
12 calculations and analyses. You talked about the  
13 ones you've performed. In your work in this case,  
14 did you look at and review the types of  
15 calculations, the engineering analyses, that Bard  
16 performed?

17 A I reviewed finite element calculations  
18 that they performed.

19 Q And do you have an opinion about whether  
20 those were sufficient or adequate?

21 A Almost all of them were inadequate for  
22 various reasons.

23 Q What were the reasons, among the reasons,  
24 please?

25 A Well, some of the reasons were that it was

## In Re: Bard IVC Filters Products Liability

Page 321

1 various -- of the two filters that play similar  
2 roles in the two filters.

3 Q The medical articles that you've reviewed  
4 about the Simon nitinol filter, including the  
5 Poletti, have those affected your opinions at all?

6 A No, they have not affected my opinions.

7 Q Do those articles support your opinion  
8 that the Bard is a better filter -- I mean that the  
9 Simon nitinol is a better filter in terms of  
10 failures?

11 A Since the Poletti article comments that  
12 the Simon nitinol filter is a safe filter, I use  
13 that information in the paper to support my view  
14 that the Simon nitinol is a safer filter than the  
15 other ones.

16 Q All right. Now, let's talk about your  
17 case-specific opinions. To arrive at the opinions  
18 you did in each of the five Bellwether cases, [REDACTED]

[REDACTED],  
20 correct?

21 A Correct.

22 Q Was it necessary for you to do any  
23 calculations specific to those patients?

24 A No, because the failures that were  
25 observed in them were consistent with the

**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit J-A - REDACTED**

PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:

DISCHARGE SUMMARY

DATE OF ADMISSION:

DATE OF DISCHARGE:

RESIDENT

DATE OF BIRTH

DISCHARGE DIAGNOSIS

OTHER DISCHARGE DIAGNOSES

PRINCIPAL PROCEDURES PERFORMED

BRIEF HOSPITAL COURSE

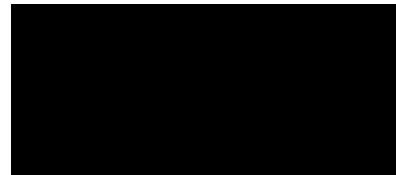
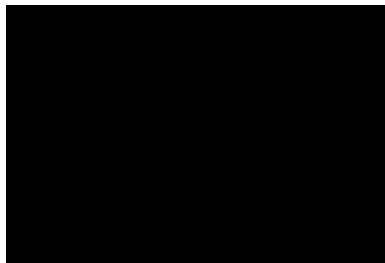
DISCHARGE SUMMARY- Page 1 of 3

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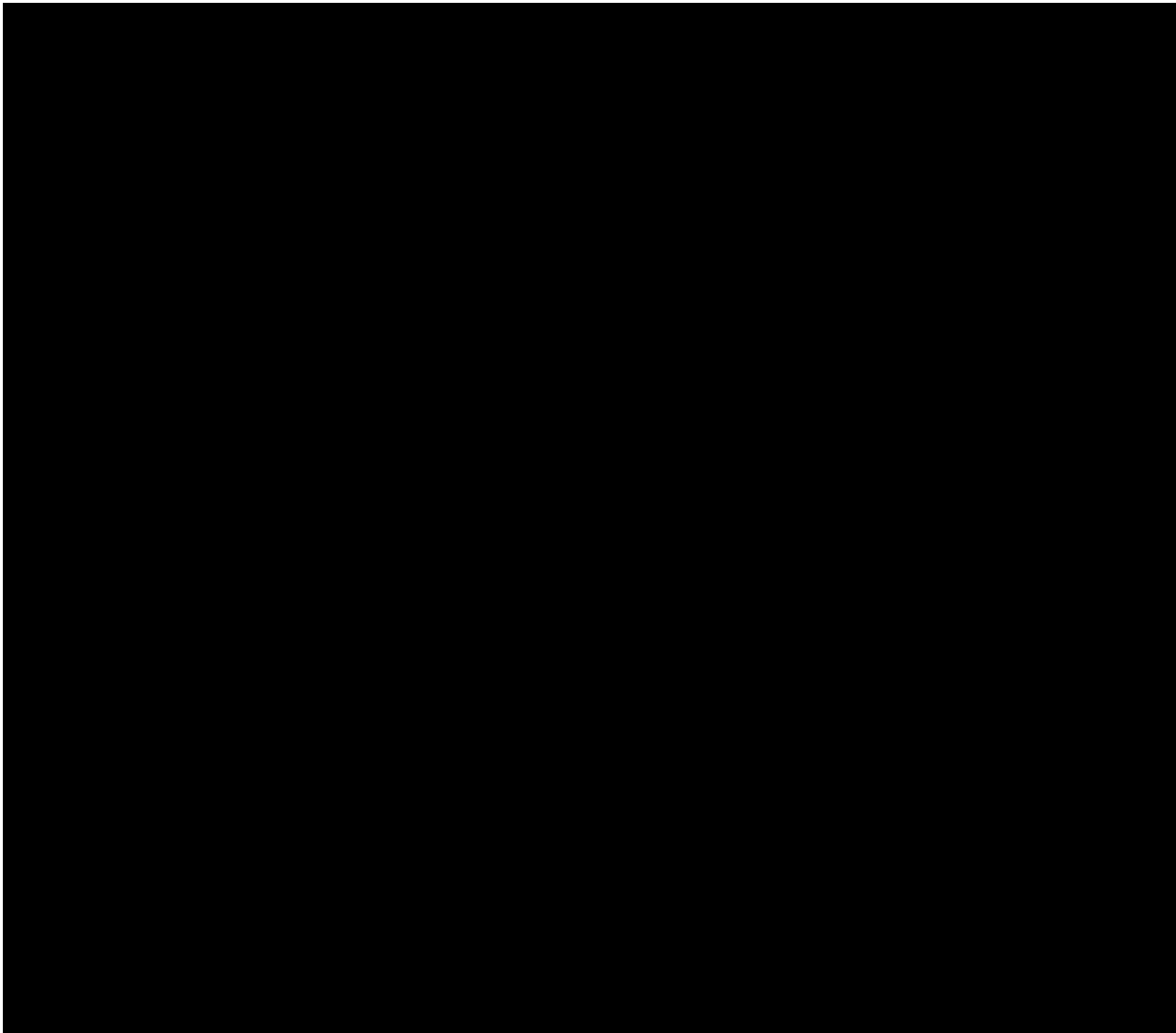
DATE 11/17/2015

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PATIENT NAME:  
MEDICAL RECORD #:  
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DISCHARGE SUMMARY



DISCHARGE DISPOSITION



DISCHARGE SUMMARY- Page 2 of 3

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DICTATING PHYSICIAN:  
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DATE OF BIRTH:

DISCHARGE SUMMARY

CD/dfg

D:  
T:  
Job  
cc:

DISCHARGE SUMMARY- Page 3 of 3

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PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:

HISTORY AND PHYSICAL

DATE OF ADMISSION:

ATTENDING PHYSICIAN

RESIDENT PHYSICIAN

INTERN PHYSICIAN

CHIEF COMPLAINT

HISTORY OF PRESENT ILLNESS

PAST MEDICAL HISTORY

HISTORY AND PHYSICAL- Page 1 of 5

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PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:

HISTORY AND PHYSICAL

MEDICATIONS

ALLERGIES

PAST SURGICAL HISTORY

SOCIAL HISTORY

FAMILY HISTORY

REVIEW OF SYSTEMS

CONSTITUTIONAL:

EYES:

EARS, NOSE, AND THROAT:

CARDIOVASCULAR:

RESPIRATORY:

GASTROINTESTINAL:

GENITOURINARY:

MUSCULOSKELETAL:

NEUROLOGIC:

ENDOCRINE:

PSYCHIATRIC:

INTEGUMENT:

HEME/LYMPH:

LABS

HISTORY AND PHYSICAL- Page 2 of 5

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PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:

HISTORY AND PHYSICAL

PHYSICAL EXAMINATION

VITAL SIGNS:

CONSTITUTIONAL:

EYES:

EARS, NOSE, AND THROAT:

NECK:

CARDIOVASCULAR:

RESPIRATIONS:

MUSCULOSKELETAL:

INTEGUMENT:

LYMPH:

NEUROLOGIC:

PSYCH:

GU:

BREAST:

ASSESSMENT AND PLAN

1.

PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:

HISTORY AND PHYSICAL

HISTORY AND PHYSICAL- Page 4 of 5

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PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
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DATE OF BIRTH:

HISTORY AND PHYSICAL

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HISTORY AND PHYSICAL- Page 5 of 5

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PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:

OPERATIVE REPORT

DATE OF OPERATION:

PREOPERATIVE DIAGNOSIS

POSTOPERATIVE DIAGNOSIS

PROCEDURE PERFORMED

ANESTHESIA

ATTENDING SURGEON

RESIDENT SURGEON

FINDINGS

COMPLICATIONS

DRAINS/PROSTHESIS

OPERATIVE NOTE- Page 1 of 5

CONFIDENTIAL

PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:

OPERATIVE REPORT

SPECIMEN

ESTIMATED BLOOD LOSS

IV FLUIDS

URINE OUTPUT

MONITORING LINES

CONDITION POSTOPERATIVELY

INDICATIONS FOR PROCEDURE

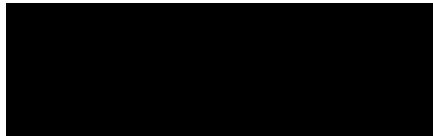
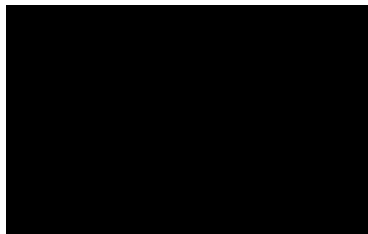
DESCRIPTION OF PROCEDURE

OPERATIVE NOTE- Page 2 of 5

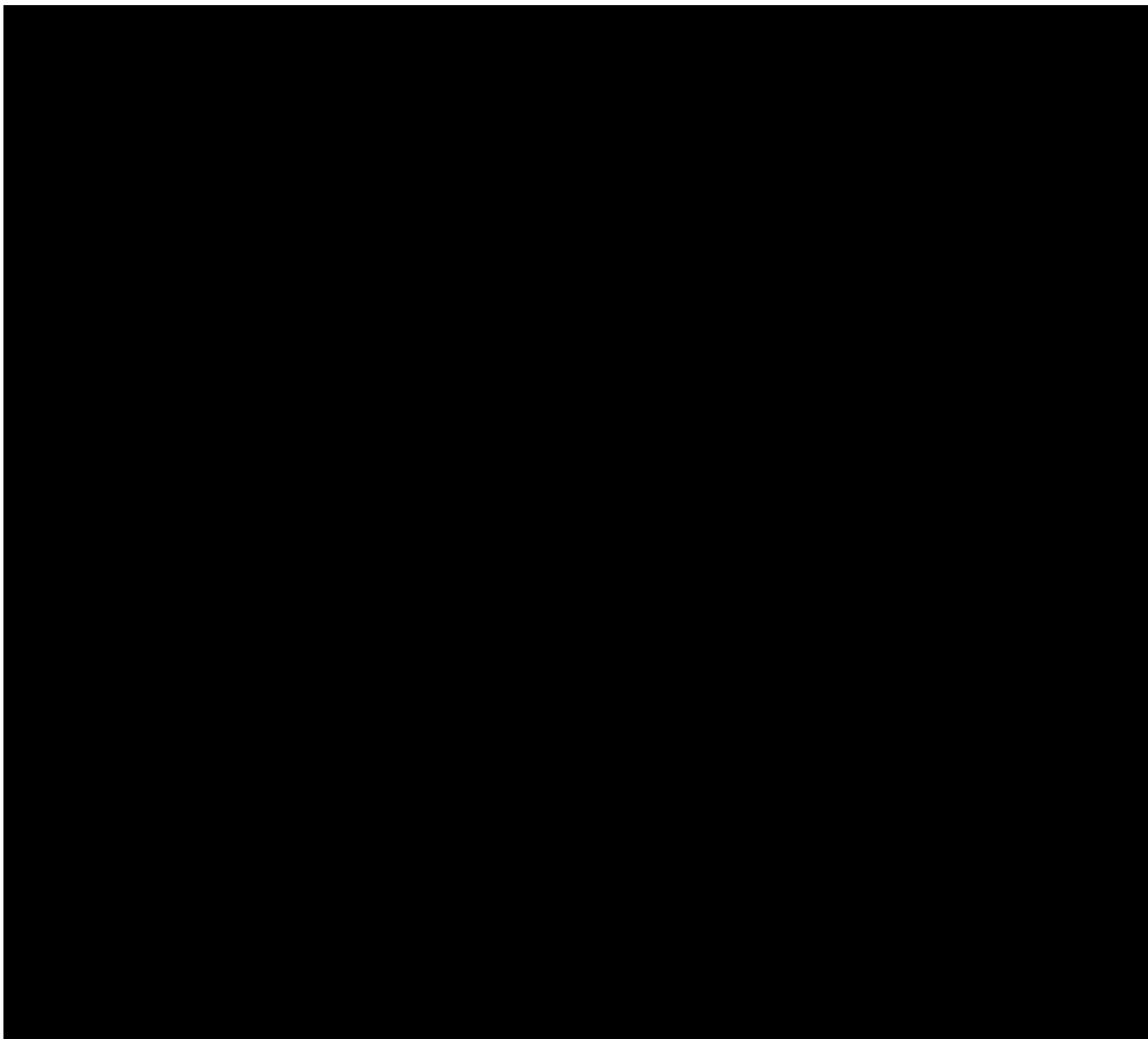
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MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
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ROOM AND BED:



OPERATIVE REPORT



OPERATIVE NOTE- Page 3 of 5



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PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
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ROOM AND BED:

OPERATIVE REPORT

[REDACTED]

[REDACTED]

AC/zpc

OPERATIVE NOTE- Page 4 of 5

[REDACTED]  
[REDACTED]

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[REDACTED]

PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
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OPERATIVE REPORT

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T:  
Job  
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OPERATIVE NOTE- Page 5 of 5

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MEDICAL RECORD #:  
BILLING #:  
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CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:

OPERATIVE REPORT

DATE OF OPERATION:

PREOPERATIVE DIAGNOSIS

POSTOPERATIVE DIAGNOSIS

PROCEDURES PERFORMED

INDICATIONS

DESCRIPTION OF PROCEDURE

INTERPRETATION OF CAVAGRAM:

OPERATIVE NOTE- Page 1 of 2

CONFIDENTIAL

PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:

OPERATIVE REPORT

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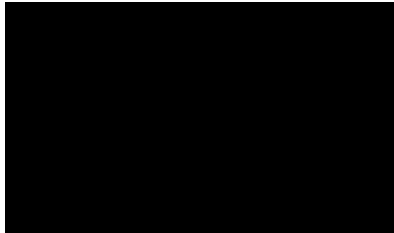
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OPERATIVE NOTE- Page 2 of 2

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PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:



DISCHARGE SUMMARY

DATE OF ADMISSION:



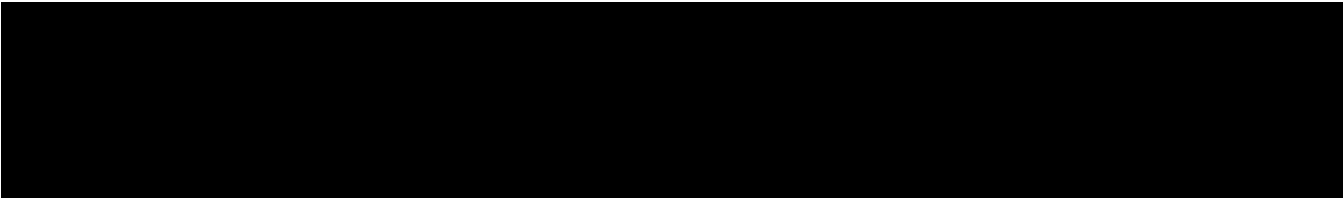
DISCHARGE DATE:



INTERN:



ADMITTING DIAGNOSIS(ES) :



DISCHARGE DIAGNOSIS(ES) :



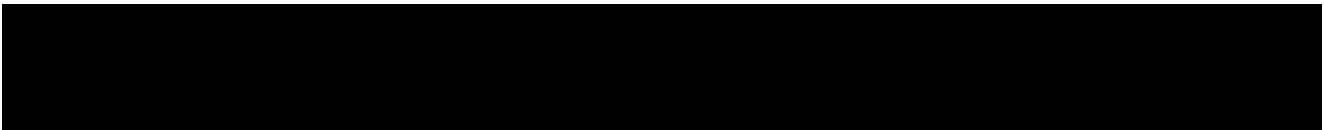
CONSULTANTS INVOLVED:



LABORATORY DATA:



IMAGING:



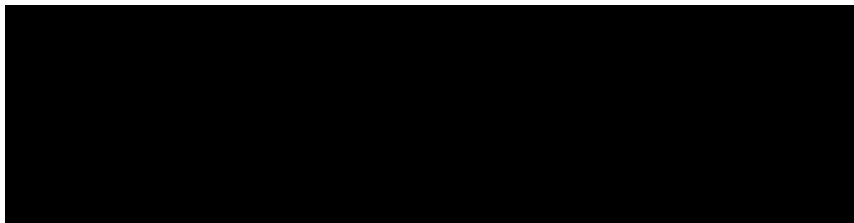
DISCHARGE SUMMARY - Page 1 of 3



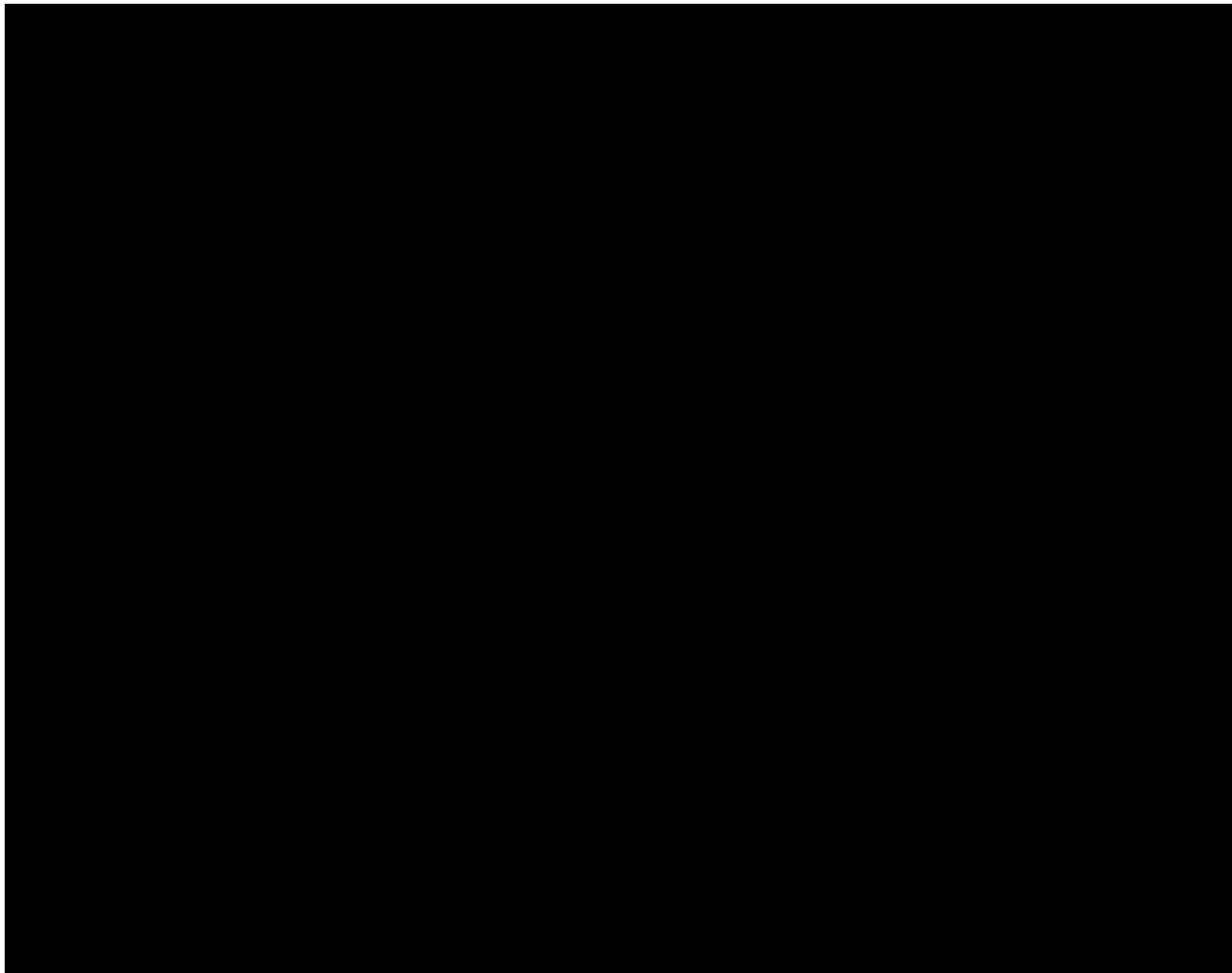
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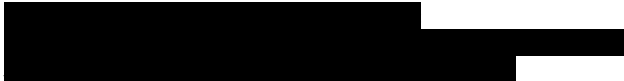
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MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:



DISCHARGE SUMMARY



DISCHARGE MEDICATIONS:



DISCHARGE SUMMARY - Page 2 of 3



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PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:

DISCHARGE SUMMARY

DISCHARGE FOLLOWUP:

FOLLOWUP ISSUES:

DC/MODL

D:

T:

Job

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DISCHARGE SUMMARY - Page 3 of 3

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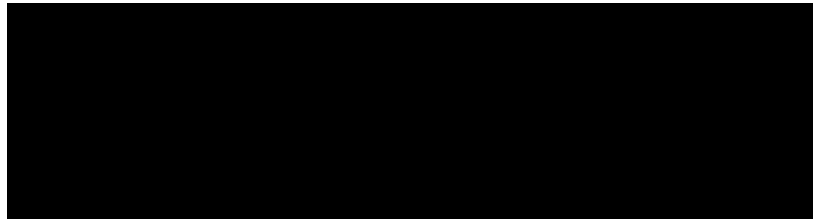
**Imaging Results**

Result time:

**Final result**

Please enter a Disposition for this patient

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MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
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ROOM AND BED:  
DATE OF BIRTH:

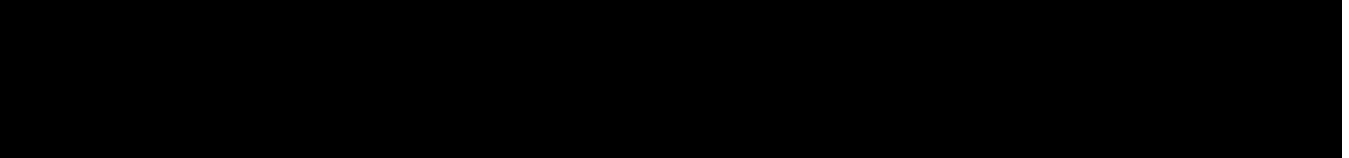


OPERATIVE REPORT

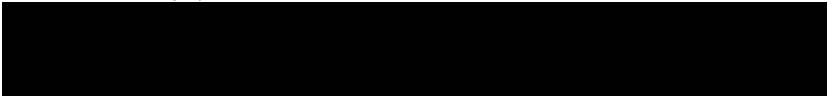
DATE OF OPERATION:



POSTOPERATIVE DIAGNOSIS (ES) :



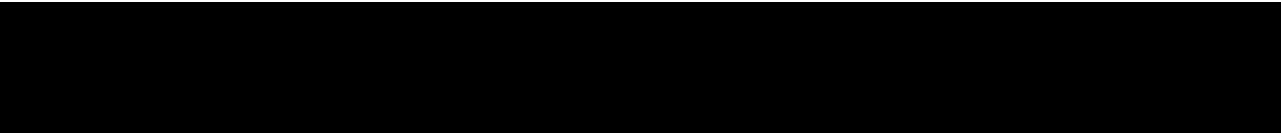
OPERATION(S) PERFORMED:



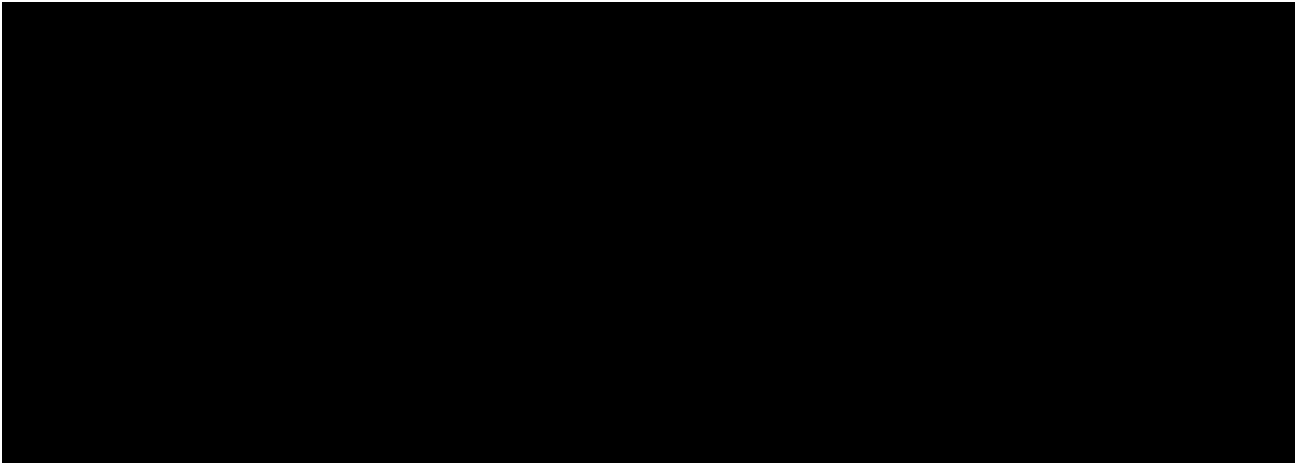
SURGEON:



CLINICAL HISTORY:



DESCRIPTION OF OPERATION:



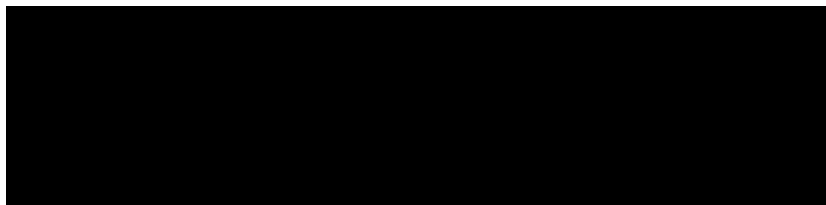
Operative Report - Page 1 of 2



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PATIENT NAME:  
MEDICAL RECORD #:  
BILLING #:  
DICTATING PHYSICIAN:  
CO-SIGNING PHYSICIAN:  
ROOM AND BED:  
DATE OF BIRTH:



OPERATIVE REPORT



IMPRESSION:



KN/MODL

D: [REDACTED]  
T: [REDACTED]  
Job [REDACTED]  
cc: [REDACTED]

Operative Report - Page 2 of 2

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**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit J-B - REDACTED**

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UNITED STATES DISTRICT COURT  
DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS ) Case No.  
PRODUCTS LIABILITY LITIGATION ) MD-15-02641-PHX-DGC

---

DO NOT DISCLOSE  
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF [REDACTED]  
March 23, 2017  
Savannah, Georgia  
4:06 p.m.

Reported by: Karen Kidwell, RMR, CRR  
GOLKOW TECHNOLOGIES, INC.  
877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

1 BY MR. COMBS:

2 Q. If a medical device manufacturer learns  
3 that a device is less safe than alternative  
4 treatments or other alternative products by other  
5 competitors, would you expect them to report that to  
6 you and other doctors?

7 A. I mean, we certainly always expect that  
8 they report anything that's not safe to the FDA and  
9 to the physicians.

10 Q. And you need to know information about  
11 safety to make informed decisions about using  
12 products?

13 A. True.

14 Q. And because you're advising patients, and  
15 they can't make informed consent about using products  
16 unless you have all the information to inform them.  
17 True?

18 A. True.

19 Q. And the information that a medical device  
20 manufacturer provides to you about their product, you  
21 would expect that to be accurate and complete. True?

22 A. Sure, to the best -- you know, certainly  
23 to the best of whatever knowledge they have acquired  
24 regarding safety and problems.

25 Q. Right. They can't leave out, though,

1 rest of their life.

2 So it really becomes a spectrum of a  
3 risk/benefit ratio. Which is really what -- true  
4 with all surgery and all medical devices: What's the  
5 risk of doing it and the risk of not doing it?

6 Q. And for the retrievable filters, I'll ask  
7 kind of a compound question. When are they removed,  
8 and who decides to remove them?

9 A. Well, in general, in the country and the  
10 world, frequently no one. A lot of times they're  
11 just left in place. I mean, the majority of them are  
12 left in place.

13 More recently, it could be whoever, you  
14 know, comes to the awareness that the filter is in  
15 place and might not any longer have a risk, a  
16 favorable risk/benefit ratio, and so that could be  
17 anyone. It could be the implanting physician. It  
18 could be the patient. It could be the primary care  
19 physician. You know, could be any of their  
20 specialists.

21 Q. And I guess, since you've been here in  
22 this practice, Savannah, for -- since completing your  
23 training, since you've been here, what IVC filter  
24 models have you used, including up until today?  
25 Which ones do you use?

1           A.    We have predominantly always used -- I  
2   won't say "always"; we have predominantly used the  
3   Bard filters. The G2 and the Simon Nitinol was the  
4   nonretrievable, and the Meridian and now the Denali.  
5   And a couple in between. They've changed every few  
6   years.

7                   Now there's even a nifty app for the  
8   iPhone, because it's gotten so complicated with all  
9   the different filter devices.

10          Q.    And why have -- well, when you say -- when  
11   you talk about using predominantly Bard IVC filters,  
12   does that go for your whole practice group here?

13          A.    Predominantly. You know, there's Cook  
14   filters, and there's other competitors' filters.  
15   There's the original Greenfield IVC filter. But we  
16   have mostly always stocked -- I would say yes,  
17   definitely yes, the majority of them that we see  
18   placed by myself and all my partners have always been  
19   the Bard filters.

20          Q.    And why is that?

21          A.    They've just always had the reputation of  
22   having the best filters. There has been the most  
23   data on them, and I think they're likely -- it's  
24   certainly variable from institution to institution,  
25   but everywhere I've been, they've been the



1 and what -- and what the complications were. But,  
2 you know, the hard part is telling you what the exact  
3 time frame of all that was.

4 Q. Okay. That's fair. And we'll get to it  
5 shortly, but the -- [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

9 Q. Do you recall any conversations with  
10 Ms. Vilece or anyone else at Bard about the Eclipse,  
11 specifically, and if so, what they told you about the  
12 Eclipse?

13 A. I really don't. I don't have specific  
14 recollection about the individual devices, except  
15 that, you know, the G2 I think was the one that was  
16 known to be the biggest problem, whenever that became  
17 evident, and then was quickly replaced.

18 Q. And when you say the G2 became the biggest  
19 problem, what was the problem with the G2?

20 A. That's the device that had the biggest  
21 reports about migrations and fractures in the device.

22 Q. And was it a kind of thing where you guys  
23 collectively, at the practice, liked using the Bard  
24 IVC filters, and so whenever they came out with a new  
25 one, you would just kind of incorporate and adopt the

1 out of an IFU, cautiously, and just have become  
2 standard of care.

3           There's lots of examples of things we  
4 still use appropriately that might not be in the IFU.  
5 But, in general, we certainly consider the IFU, and  
6 -- because that's what the research was done on for  
7 certain devices, and that's what the FDA is  
8 recommending, and that's what the company -- and  
9 typically, that's very strongly what the company  
10 recommends.

11           Q. And do you read the IFU?

12           A. Sometimes. I mean, I have read them. I  
13 don't -- certainly don't read them on every package,  
14 because they're the same from the same device, but --  
15 you know, not -- not all the time, but it does come  
16 up, for example, at meetings, or you're reading about  
17 and someone's discussing an issue with an IFU. You  
18 know, if something is within the IFU or not, to help  
19 define things that might be outside of the IFU but  
20 still medically indicated.

21           Q. Do you know if you ever read the IFU for  
22 the Eclipse IVC filter?

23           A. Not that I recall.

24           Q. Okay. And IFUs have warnings on them of  
25 side effects, complications, things like that, also?

1 A. Yes.

2 Q. And even if you haven't read the Eclipse  
3 IFU, you're probably generally familiar with IVC  
4 filter IFUs, if they warn of things like fractures,  
5 migration, perforation, tilt; complications like  
6 that. Right?

7 A. Yes. Yes.

8 Q. But is it your understanding these  
9 complications are rare, for IVC filters?

10 A. Well, depends how you define "rare." I  
11 mean, back -- originally, when we were implanting  
12 filters 15, 20 years ago, everyone thought they were  
13 rare.

14 Now people think they're -- reached a  
15 peak, and reached a peak in frequency, and then we  
16 think that now they're -- they're less frequent than  
17 they were before. So it's been a migrating target in  
18 terms of what the risks are or what our understanding  
19 of the risks are.

20 Q. If you can recall your mindset in

21 [REDACTED]

22 [REDACTED] what was your understanding of the rarity of  
23 complications from IVC filters then?

24 A. I don't have independent recollection of  
25 placing that particular filter, but the best I can

1 tell from that date and from my note, is that that  
2 is -- that predates the peak of my concern and the  
3 release of the warnings about the complications of  
4 filters.

5 Q. You've learned more about filters since  
6 then --

7 A. Right.

8 Q. -- and their complications?

9 A. Right.

10 Q. If Bard knew about complications with its  
11 filters at that time, [REDACTED]

12 [REDACTED] you would have wanted to know that,  
13 right?

14 A. Yes.

15 Q. I may have asked you this already, but do  
16 you have a specific recollection of [REDACTED]

17 A. No.

18 Q. And that's certainly understandable for  
19 someone you saw briefly seven years ago, right?

20 A. Right, right.

21 MR. COMBS: I think we already marked the  
22 op notes, right, 4017? Here we are.

23 (Exhibit 4017 was previously marked for  
24 identification.)  
25

1 BY MR. COMBS:

2 Q. Doctor, throughout the rest, I'll  
3 probably show you a bunch of exhibits. We'll start  
4 with your op notes, and I may have some other things  
5 that go with that we'll mark. If we can, let's just  
6 go ahead and mark --

7 MS. DALY: Just tell me the Bates numbers  
8 on the bottom of where you're going.

9 MR. COMBS: We'll start with just the  
10 Exhibit 4017, on the op report, but I'm also  
11 going to look at 1292 and 1506 and 7, the  
12 consent forms, and then another of the -- the  
13 label. And that will be it.

14 BY MR. COMBS:

15 Q. So in front of you now, Doctor,  
16 Exhibit 4017, [REDACTED]

17 [REDACTED] Correct?

18 A. Yes.

19 [REDACTED]

20 [REDACTED]

21 Q. And, again, as far as you know, that's the  
22 only time you ever saw her or interacted with her or  
23 treated her, that date?

24 [REDACTED]

[REDACTED]

1     There probably would be some note in the medical  
2     record from the hospital, but I never -- it's not  
3     part of our record, our medical record.

4             (Exhibit 4018 was marked for identification.)

5     BY MR. COMBS:

6             Q.     And I think you're actually right.   And  
7     what you've been handed here, Exhibit 4018, is some  
8     other medical records, including the consent forms  
9     for the procedure.   [REDACTED]

[REDACTED]   [REDACTED]   [REDACTED]

11            A.     Yes.   So I -- there is almost always a  
12     consultation, though, before, just when we see the  
13     patient, make the decision, talk to the patient,  
14     consider the data in order to communicate back to the  
15     other physicians.   So there would have been some  
16     other note.

17            Q.     [REDACTED]

[REDACTED]   [REDACTED]

[REDACTED]   [REDACTED]   And so to the  
20     extent you need to refer back to any of this -- and  
21     I'll ask you some specific questions about this,  
22     too -- but if you need to look at any of this to  
23     refresh your recollection, go ahead.

24            [REDACTED]

[REDACTED]   [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

5           A.     Just slightly short of that, because it  
6     retains the option to remove it, because if a filter  
7     does clot off, it's a problem if you can't remove it.  
8     So there's some advantages to having a retrievable  
9     filter, if you, even if you think it's going to stay  
10    in long term.

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

14           Q.     And then around that same section we were  
15    just looking at there, maybe the same sentence,  
16    there, in the indications, on the first page of your  
17    op report, it says: [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

1           A.    Not really, because some people have  
2    very -- I would say the majority of people have a  
3    more clear indication for permanent filter or have a  
4    more clear indication for a temporary filter. ■

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

9           Q.    And I want to ask about a little bit -- a  
10   different portion of that sentence, though. ■

■ [REDACTED]

■ [REDACTED]

■           ■ [REDACTED]

■ [REDACTED] ■

■ [REDACTED]

16          Q.    Okay.

17          A.    [REDACTED]

■ [REDACTED] [REDACTED]

■ [REDACTED]

■ [REDACTED] [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

25          Q.    And that would be your practice, right?



1 anymore.

\_\_\_\_\_

\_\_\_\_\_

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| Year | Number of cases | Percentage of cases |
|------|-----------------|---------------------|
| 2010 | 10              | 10.0%               |
| 2011 | 15              | 15.0%               |
| 2012 | 20              | 20.0%               |
| 2013 | 25              | 25.0%               |
| 2014 | 30              | 30.0%               |
| 2015 | 35              | 35.0%               |
| 2016 | 40              | 40.0%               |
| 2017 | 45              | 45.0%               |
| 2018 | 50              | 50.0%               |
| 2019 | 55              | 55.0%               |
| 2020 | 60              | 60.0%               |
| 2021 | 65              | 65.0%               |
| 2022 | 70              | 70.0%               |
| 2023 | 75              | 75.0%               |
| 2024 | 80              | 80.0%               |
| 2025 | 85              | 85.0%               |
| 2026 | 90              | 90.0%               |
| 2027 | 95              | 95.0%               |
| 2028 | 100             | 100.0%              |
| 2029 | 105             | 105.0%              |
| 2030 | 110             | 110.0%              |
| 2031 | 115             | 115.0%              |
| 2032 | 120             | 120.0%              |
| 2033 | 125             | 125.0%              |
| 2034 | 130             | 130.0%              |
| 2035 | 135             | 135.0%              |
| 2036 | 140             | 140.0%              |
| 2037 | 145             | 145.0%              |
| 2038 | 150             | 150.0%              |
| 2039 | 155             | 155.0%              |
| 2040 | 160             | 160.0%              |
| 2041 | 165             | 165.0%              |
| 2042 | 170             | 170.0%              |
| 2043 | 175             | 175.0%              |
| 2044 | 180             | 180.0%              |
| 2045 | 185             | 185.0%              |
| 2046 | 190             | 190.0%              |
| 2047 | 195             | 195.0%              |
| 2048 | 200             | 200.0%              |
| 2049 | 205             | 205.0%              |
| 2050 | 210             | 210.0%              |
| 2051 | 215             | 215.0%              |
| 2052 | 220             | 220.0%              |
| 2053 | 225             | 225.0%              |
| 2054 | 230             | 230.0%              |
| 2055 | 235             | 235.0%              |
| 2056 | 240             | 240.0%              |
| 2057 | 245             | 245.0%              |
| 2058 | 250             | 250.0%              |
| 2059 | 255             | 255.0%              |
| 2060 | 260             | 260.0%              |
| 2061 | 265             | 265.0%              |
| 2062 | 270             | 270.0%              |
| 2063 | 275             | 275.0%              |
| 2064 | 280             | 280.0%              |
| 2065 | 285             | 285.0%              |
| 2066 | 290             | 290.0%              |
| 2067 | 295             | 295.0%              |
| 2068 | 300             | 300.0%              |
| 2069 | 305             | 305.0%              |
| 2070 | 310             | 310.0%              |
| 2071 | 315             | 315.0%              |
| 2072 | 320             | 320.0%              |
| 2073 | 325             | 325.0%              |
| 2074 | 330             | 330.0%              |
| 2075 | 335             | 335.0%              |
| 2076 | 340             | 340.0%              |
| 2077 | 345             | 345.0%              |
| 2078 | 350             | 350.0%              |
| 2079 | 355             | 355.0%              |
| 2080 | 360             | 360.0%              |
| 2081 | 365             | 365.0%              |
| 2082 | 370             | 370.0%              |
| 2083 | 375             | 375.0%              |
| 2084 | 380             | 380.0%              |
| 2085 | 385             | 385.0%              |
| 2086 | 390             | 390.0%              |
| 2087 | 395             | 395.0%              |
| 2088 | 400             | 400.0%              |
| 2089 | 405             | 405.0%              |
| 2090 | 410             | 410.0%              |
| 2091 | 415             | 415.0%              |
| 2092 | 420             | 420.0%              |
| 2093 | 425             | 425.0%              |
| 2094 | 430             | 430.0%              |
| 2095 | 435             | 435.0%              |
| 2096 | 440             | 440.0%              |
| 2097 | 445             | 445.0%              |
| 2098 | 450             | 450.0%              |
| 2099 | 455             | 455.0%              |
| 2100 | 460             | 460.0%              |

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|   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |     |
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| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 | 55 | 56 | 57 | 58 | 59 | 60 | 61 | 62 | 63 | 64 | 65 | 66 | 67 | 68 | 69 | 70 | 71 | 72 | 73 | 74 | 75 | 76 | 77 | 78 | 79 | 80 | 81 | 82 | 83 | 84 | 85 | 86 | 87 | 88 | 89 | 90 | 91 | 92 | 93 | 94 | 95 | 96 | 97 | 98 | 99 | 100 |
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\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

[REDACTED]

\_\_\_\_\_

\_\_\_\_\_

[REDACTED]

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_

\_\_\_\_\_

1 BY MR. COMBS:

2 Q. Sure. No, no problem. I'll withdraw the  
3 question.

4 Other than myself and my colleagues, have  
5 you talked about [REDACTED]

6 [REDACTED]  
7 A. Briefly with [REDACTED] who -- I think  
8 she was the one who told me that, you know, there was  
9 an e-mail that we -- that was sent to us about [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED] and that -- you know, that there was  
13 this litigation.

14 Q. Okay.

15 A. That was about -- about the extent of it,  
16 and that it was -- [REDACTED]

17 [REDACTED]

18 [REDACTED] and that's all she knew.

19 Q. Anyone else that you've talked to besides  
20 her?

21 A. No.

22 Q. Okay. We can move those aside, because  
23 I'm going to show you some other documents.

24 We've talked about the different models of  
25 the Bard IVC filters over the years. Were you aware

1 that one of the reasons that Bard came out with the  
2 different versions of its IVC filters was to try to  
3 address problems with its filters fracturing?

4 A. Yes. In that, you know, there were  
5 always -- we know there were always complications,  
6 some complications of them and that they were -- you  
7 know, it just seemed like the filters were similar to  
8 all of the stents we used, the -- basically, there's  
9 always one out in the market and there's one always  
10 under R&D that's the next generation, trying to  
11 improve upon either patency or lower complications  
12 or -- so we knew there was always one, you know, just  
13 from this pattern, it became evident that there was  
14 always another -- another one -- another one coming.  
15 If that answers your questions.

16 Q. Another model of the Bard IVC filters  
17 coming?

18 A. Right, right.

19 Q. Do you have any idea what those rates of  
20 complications or fractures were for Bard IVC filters  
21 or any other manufacturer?

22 A. I mean, we were given different -- you  
23 know, you would hear different numbers from different  
24 sources. You'd hear a different presentation at a  
25 talk, that might talk about certain complications

1 based on one study, and then there's retrospective  
2 studies; there's the meta-analyses of combining  
3 multiple studies.

4 So there is -- there just is no one  
5 answer, you know, to tell you that there was any  
6 specific number. But I don't have a specific number  
7 in my mind. But certainly not back years ago.

8 Q. Right. Do you -- do you have any, like,  
9 ballpark in your head of what would be an acceptable  
10 rate of fractures for an IVC filter?

11 A. No. I mean, obviously we want it to be  
12 very low. Our initial understanding was that the  
13 fracture rate was very low, in the 5 percent range;  
14 and then at some point, you know, maybe in the last  
15 four years or so, is when we learned that they were  
16 higher than that. Or maybe six years, or three,  
17 or ...

18 Q. Let's see here. Get stuff together here.

19 (Exhibit 4019 was marked for identification.)

20 BY MR. COMBS:

21 Q. And you know what, we'll make it easy --  
22 we can use that one. That's fine.

23 MR. STOLLER: It's been previously marked.

24 You can use the same number, but that's okay.

25 MR. COMBS: Are we using the same number?

1           have changed anything, because I'd assume -- I  
2           didn't assume they did know a cause of the limb  
3           detachments, because if they did, I thought that  
4           would be something that was fixed. It just  
5           wasn't my understanding that they -- it was kind  
6           of my understanding that they didn't know the  
7           cause of it, just like the limitations of stents  
8           and other devices.

9       BY MR. COMBS:

10           Q.     Understood. Turn to the right -- the  
11           lower right corner of 884.

12           A.     Okay.

13           Q.     And there's a box up towards the top of  
14           the page, and either the last or second-to-last  
15           sentence there, in the top paragraph of the box,  
16           says: "Recovery filter fracture rates exceed the  
17           rates reported by other manufacturers in the MAUDE  
18           database."

19                     Do you see that?

20           A.     Yes.

21           Q.     Is that information you would have wanted  
22           to know in 2004?

23           A.     Yes, if there's a higher fracture rate,  
24           yes.

25                     (Exhibit 4024 was marked for identification.)

1 BY MR. COMBS:

2 Q. Turning to the next one, if you could,  
3 with me, Doctor, so we can move things along. And I  
4 would be happy to leave you copies of this  
5 afterwards. I've got copies for you if you want.

6 If you want to turn to the next one,  
7 Doctor?

8 A. Oh, the next document?

9 Q. That's marked 4024.

10 A. Okay.

11 Q. And this is a Health Hazard Evaluation,  
12 December 17th, 2004, Bard?

13 A. Agreed.

14 Q. And on the second page, under number 2, A,  
15 see there, it says: "Reports of death, filter  
16 migration (movement), IVC perforation, and filter  
17 fracture associated with Recovery filter were seen in  
18 the MAUDE database at reporting rates that were 4.6,  
19 4.4, 4.1 and 5.3 higher, respectively, than reporting  
20 rates for all other filters."

21 Is that information you wanted, that Bard  
22 knew in December 2004, and that would have been  
23 important to you?

24 A. Yes.

25 Q. And then number 3, just below that, the

1 specific sentences.

2 First of all, the sentence begins if it --

3 "If one were to extrapolate our observed

4 prevalence of filter fractures ..."

5 I mean, that, right off the bat, in our

6 training, is to not extrapolate observed

7 prevalence rates of something, because there's a

8 lot of other error and factors in that.

9 So this, again, in general, yes; in

10 particular, the sentence -- you know, I don't

11 know what to make of that sentence, because it's

12 very vague.

13 BY MR. COMBS:

14 Q. And -- but the fracture rates they're

15 reporting here aren't vague. True?

16 A. Correct. You're right.

17 Q. And is that information that would have

18 been important for you in deciding to use Bard IVC

19 filters?

20 A. Yes. All of the fracture information rate

21 is something that was important to consider in the

22 decision.

23 (Exhibit 4026 was marked for identification.)

24 BY MR. COMBS:

25 Q. And the next one here is another e-mail

1 chain between David Ciavarella and some other Bard  
2 people. And I will -- I don't know if it says it in  
3 this chain or not; I think -- it doesn't look like it  
4 does, but I'll represent to you that David Ciavarella  
5 was the medical director for Bard at this time  
6 period, in December 2005.

7 And at the bottom of the first page, he  
8 states: "The G2 is a permanent filter; we also have  
9 one (the SNF) that has virtually no complaints  
10 associated with it. Why shouldn't doctors be using  
11 that one rather than the G2?"

12 And my question is: Is that information  
13 that would have been important to you, to know that  
14 the medical director for Bard in 2005 was questioning  
15 why Bard was pushing the G2 as a permanent filter  
16 when they already had the SNF one?

17 MS. DALY: Object to the form. Lack of  
18 foundation.

19 THE WITNESS: You know, again, all  
20 information is helpful, if there's -- if it is  
21 information regarding concern about one filter  
22 being better than the other.

23 BY MR. COMBS:

24 [REDACTED]  
[REDACTED]



**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit J-C - REDACTED**



5900T

Name of Patient: [REDACTED]

Physician provider of information about procedure: [REDACTED]

(A) (1) I acknowledge and understand that the following procedure(s) (including procedures and/or additional services, such as anesthesia, radiology, pathology and the like) including which has (have) been described to me is (are) to be performed on the patient,

Procedure: [REDACTED]

and that as a result of the performance of the procedure(s) there is a material risk that the patient may suffer infection, allergic reaction, severe loss of blood, loss or loss of function of any limb or organ, paralysis, paraplegia or quadriplegia, disfiguring scar, brain damage, cardiac arrest, or death. In addition to the above, anesthetic procedures may also result in dental or nerve injury, headache or backache.

(2) I acknowledge and understand that during the course of the procedure(s) described in subparagraph (A) (1) above, conditions may develop which may reasonably necessitate an extension of the original procedure(s) or the performance of procedure(s) which are unforeseen or not known to be needed at the time this consent is obtained. I therefore consent to and authorize the persons described in the last paragraph of this consent to make the decisions concerning the performance of and to perform such procedure(s) as they may deem reasonably necessary or desirable in the exercise of their professional judgement, including those procedures that may be unforeseen or not known to be needed at the time this consent is obtained. This consent shall also extend to the treatment for all conditions which may arise during the course of such procedures including those conditions which may be unknown or unforeseen at the time consent is obtained.

(B) The anesthesia considered suitable for this type of surgery/procedure has been presented to me in general terms through methods such as direct communications, videotapes, audiotapes, pamphlets or booklets. The Anesthetic Plan, including the method of administration, will be discussed with me by a member of the anesthesia group before the administration of any anesthetic medication. My anesthetic will be administered by an anesthesiologist, or an anesthesiologist under the direct supervision and control of an anesthesiologist.

(C) I acknowledge and understand and duly evidence in writing by executing this form that I have been informed in general terms of the following,

- (1) A diagnosis of the condition requiring the procedure(s)
- (2) The nature and purpose of the procedure(s)
- (3) The material risks of the procedure(s) (see paragraph (A) above)
- (4) The likelihood of success of the procedure(s)
- (5) The practical alternatives to such procedure(s), if any, and
- (6) The prognosis if the procedure(s) is (are) rejected and that all were provided through the use of video tapes, audio tapes,

pamphlets, booklets, or other means of communication or through conversations with the responsible physician, or other medical personnel under the supervision and control of the responsible physician, other medical personnel involved in the course of treatment, nurses, physician's assistants, trained counselors, or patient educators.

(D) I acknowledge that there are practical alternatives to the procedure(s) described in paragraph (A) which alternatives reasonably prudent physicians generally recognize and accept.

(E) I acknowledge and understand that this request for and consent to surgical or diagnostic services and anesthesia procedures shall be valid for the responsible physician, all medical personnel under the direct supervision and control of the responsible physician, and for all other medical personnel otherwise involved in the course of treatment.

I have been given ample opportunity to ask questions and any questions I have asked have been answered or explained in a satisfactory manner.

By signing below, I acknowledge that I have read or had it read or explained to me and I understand this form and I voluntarily consent to allow Dr. [REDACTED] or any physician(s) designated or selected by him or her and all medical personnel under the direct supervision and control of such physician and all other personnel which may be necessary to perform the procedures described or otherwise referred to herein.

Signature [REDACTED]

Relationship of Authorized Person [REDACTED]

Date [REDACTED]

Time [REDACTED]

**WAIVER OF RIGHT TO BE INFORMED**

I fully and completely waive the right to be informed of the information specified in paragraph (B) above and request that such information not be disclosed to me.

Signature of Patient or Authorized Person [REDACTED]

Witness [REDACTED]

Relationship of Authorized Person [REDACTED]

Date [REDACTED]

Time [REDACTED]

**CONSENT TO SURGICAL OR DIAGNOSTIC  
AND ANESTHESIA PROCEDURE(S)**

Form # NS180 (04/04)

DATE

12/28/2016

Page 1 of 2

DOB [REDACTED]



1022600161

Patient ID Area

### CONSENT FOR TRANSFUSION OF BLOOD OR BLOOD PRODUCTS

1. I consent to have blood and/or blood products transfusion(s) as may be deemed advisable by Dr. [REDACTED] or his/her designee and the risks, of refusal, benefits, and alternatives to blood or blood product transfusions have been explained to me.
2. I understand that no guarantee has been given by anyone as to the results that may be obtained.
3. Potential benefits of receiving blood or blood products include:
  - Restoring blood volume
  - Replacing clotting factors; and
  - Improving oxygen delivery to the body.
4. Potential risks of not receiving blood or blood products include:
  - Death
  - Heart attack
  - Stroke
  - Bleeding.
5. I understand that reactions are very unusual. The potential risks of blood or blood products include, but are not limited to:
  - Temporary transfusion reactions such as headache, fever, chills, rash, and difficulty breathing;
  - Hepatitis;
  - Severe transfusion reactions potentially resulting in death;
  - HIV (Human Immunodeficiency virus) (AIDS); and
  - Other infectious agents.
6. Potential alternatives to receiving community supplied blood or blood products include:
  - Donating my blood several weeks in advance;
  - Friends/relatives with compatible blood donating blood for me, if donated weeks in advance;
  - Cell saving technology (capturing and returning my own blood); and
  - Intravenous (IV) fluids to increase volume.

I, the undersigned, have had this blood / blood component and transfusion consent explained to me and fully understand the contents of this authorization.

|   |                    |                    |
|---|--------------------|--------------------|
| [REDACTED]<br>Signature of Patient or Authorized Person | [REDACTED]<br>Date | [REDACTED]<br>Time |
| [REDACTED]<br>Relationship of Authorized Person         |                    |                    |

### REFUSAL OF BLOOD OR BLOOD PRODUCTS

I refuse the use of any blood and/or blood products. I understand the risks of not receiving blood and/or blood products.

|   |         |
|---|---------|
| Signature of Patient or Authorized Person | Witness |
| Relationship of Authorized Person         | Date    |
|   | Time    |

DOB



1022600161

Patient ID Area

PRINTED BY: LAMBESA1

DATE 12/28/2016 Page 2 of 2

**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit J-I - REDACTED**

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF ARIZONA

3

4 IN RE: BARD IVC FILTERS ) Case No.

PRODUCTS LIABILITY LITIGATION ) MD-15-02641-PHX-DGC

5

6

7

8 DO NOT DISCLOSE

9 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

10

11

12 VIDEOTAPED DEPOSITION OF [REDACTED]

13 August 5, 2017

14 Winston-Salem, North Carolina

15 8:03 a.m.

16

17

18

19

20

21

22

23 Reported by: Karen Kidwell, RMR, CRR

24 GOLKOW LITIGATION SERVICES

877.370.3377 ph | 917.591.5672 fax

25

deps@golkow.com

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

5 Q. How did that direct the course that you

6 took?

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

19 [REDACTED] Again, it's hard to say, because in all of

[REDACTED] my medical experience, albeit limited, [REDACTED]

■ [REDACTED]

■ [REDACTED]. [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

1 especially with contrast, such as this.

■ ■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

7 A. I will say that again, having never seen a  
8 presentation like this, and the medical literature  
9 not being very robust on these types of  
10 presentations, [REDACTED]

■ [REDACTED]

■ [REDACTED] [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

16 Q. So what was your next step? Did you order  
17 additional tests, or what did you order?

■ ■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit J-J - REDACTED**



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UNITED STATES DISTRICT COURT  
DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS ) Case No.  
PRODUCTS LIABILITY LITIGATION ) MD-15-02641-PHX-DGC

---

DO NOT DISCLOSE  
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF [REDACTED]  
March 23, 2017  
Savannah, Georgia  
1:41 p.m.

Reported by: Karen Kidwell, RMR, CRR  
GOLKOW TECHNOLOGIES, INC.  
877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

1            A.     Correct.

- **1.1.1.1** **1.1.1.1** **1.1.1.1** **1.1.1.1**
- **1.1.1.1** **1.1.1.1** **1.1.1.1** **1.1.1.1**
- **1.1.1.1** **1.1.1.1** **1.1.1.1** **1.1.1.1**
- **1.1.1.1** **1.1.1.1** **1.1.1.1** **1.1.1.1**
- **1.1.1.1** **1.1.1.1** **1.1.1.1** **1.1.1.1**

7 Q. And how did you, to the best of your  
8 recollection, get involved in the care and treatment  
9 of [REDACTED]

| Row | Bar Length (approx. % of total width) |
|-----|---------------------------------------|
| 1   | 95                                    |
| 2   | 85                                    |
| 3   | 98                                    |
| 4   | 88                                    |
| 5   | 92                                    |
| 6   | 85                                    |
| 7   | 92                                    |
| 8   | 88                                    |
| 9   | 95                                    |
| 10  | 95                                    |

██████████ as an interventional radiologist, where you  
20 have some special expertise and abilities to actually  
21 act on this, as opposed to the radiologist who took  
22 the original films, who's not interventional, to use  
23 the word you used?

24            A.    Correct.

25 Q. Let me ask you if you would turn to page 3

[illegible]

1 [REDACTED]  
2 And I'm a little bit more conservative, I  
3 suppose, than a lot of people in my approach to a lot  
4 of different things. [REDACTED]

5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]

14 Q. Okay. And I was focusing a bit on just --  
15 the last question, [REDACTED] Did you --  
16 my -- let me make sure I understand.

17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]

21 A. Yes.

22 Q. Okay. And did you discuss -- well, let me  
23 come back to that point.

24 A. Okay.

25 Q. We will come back to that after. After

**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit J-Q - REDACTED**

1           IN THE UNITED STATES DISTRICT COURT  
2                           FOR THE DISTRICT OF ARIZONA

3                                   -   -   -

4  
5           IN RE:    BARD IVC                               :  
6           FILTERS PRODUCTS                            :   NO.  
7           LIABILITY LITIGATION                       :   MD-15-02641-  
8   :   PHX-DGC

9   :

10    :

11                                   -   -   -

12   July 18, 2017

13                                   -   -   -

14                           DO NOT DISCLOSE - SUBJECT TO FURTHER  
15   CONFIDENTIALITY REVIEW

16   Videotaped deposition of  
17           MARK W. MORITZ, M.D., taken pursuant to  
18           notice, was held at the offices McCarter  
19           & English, LLP, 100 Mulberry Street,  
20           Newark, New Jersey, beginning at 9:07  
21           a.m., on the above date, before Michelle  
22           L. Gray, a Registered Professional  
23           Reporter, Certified Shorthand Reporter,  
24           Certified Realtime Reporter, and Notary  
                  Public.

                                 -   -   -

21   GOLKOW LITIGATION SERVICES  
22   877.370.3377 ph | 917.591.5672 fax  
23   deps@golkow.com  
24

1 Q. Failures of Bard filters  
2 include tilting?

3 A. Correct.

4 Q. Failure of Bard filters  
5 include fracture?

6 A. Yes.

7 Q. Embolization?

8 A. Yes.

9 Q. And failures also include  
10 penetration into other organs, correct?

11 A. Correct.

12 Q. And you have seen at least  
13 in reviewing the plaintiff experts that  
14 there were internal documents in Bard  
15 which spoke to serious injuries, and even  
16 death caused by failure modes of Bard  
17 filters?

18 A. Correct.

19 Q. And certainly that's  
20 something I think you would agree that a  
21 medical doctor would want to know from a  
22 medical device company in making  
23 decisions about which type of devices to  
24 use for patients, fair?

1 MR. BROWN: Object to the  
2 form.

3 THE WITNESS: Yes.

4 BY MR. O'CONNOR:

5 Q. And certainly from what  
6 you've told me before, you certainly  
7 cannot discuss what if anything Bard did  
8 by way of warning of its knowledge of the  
9 types of filters and complications that  
10 Bard became aware of, true?

11 A. Well, I remember a letter  
12 around 2005 that I think I got.

13 Q. All right. So you got some  
14 kind of "Dear Colleague" or "Dear Doctor"  
15 letter?

16 A. "Dear Doctor" letter.

17 Q. You're not going to be  
18 talking about that letter in this trial,  
19 fair?

20 MR. BROWN: Object to the  
21 form.

22 THE WITNESS: No, I didn't  
23 intend to.

24



**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit M-A - REDACTED**

[REDACTED]  
[REDACTED]  
Ph: [REDACTED]

Account ID  
[REDACTED]

Guarantor Name & Address  
[REDACTED]

Visit ID  
[REDACTED]

Detailed Bill For

Patient Name:

Account Class:

Attending Physician:

Surge Admission Date:

Discharge Date:

Charges

=====

| Service | Cost | Rev. | Proc. | Description | Qty. | Amount |
|---------|------|------|-------|-------------|------|--------|
| Date    | Ctr. | Code | Code  |             |      |        |

=====

[REDACTED]

Total hospital charges:

Payments

=====

[REDACTED]

**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit M-C - REDACTED**

Do Not Disclose - Subject to Further Confidentiality Review

1 UNITED STATES DISTRICT COURT  
DISTRICT OF ARIZONA  
2 No. MD-15-02641-PHX-DGC  
3

4 In Re: Bard IVC Filters Products  
Liability Litigation  
5

DO NOT DISCLOSE - SUBJECT TO FURTHER  
6 CONFIDENTIALITY REVIEW

---

7  
WITNESS: [REDACTED]

---

8  
9 Pursuant to Fed. R. Civ. P. 26 and 30  
10 the videotaped deposition of Roderick Tompkins,  
11 M.D. was taken before Janine N. Leroux,  
12 Stenographic Court Reporter and Notary Public -  
13 Special Commission in and for the State of  
14 Kentucky at Large, at the 613 23rd Street, Suite  
15 440, Ashland, Kentucky on Tuesday, April 11,  
16 2017, commencing at the approximate hour of 4:45  
17 p.m. Said deposition was taken pursuant to  
18 Notice.  
19  
20  
21  
22  
23  
24  
25

Do Not Disclose - Subject to Further Confidentiality Review

1           be -- I will be doing the same thing on my  
2           objections.

3       BY MR. DeGREEFF:

4           Q       Has anyone from Bard ever made you  
5       aware of deaths caused by the Bard IVC filters?

6           A       No.

7           Q       If there were deaths caused by Bard IVC  
8       filters that you were using in patients, is that  
9       something you'd want to know?

10                   MS. HELM: Object to the form.

11           A       Yes.

12           Q       It would be important for you to know,  
13       right?

14           A       Yes.

15           Q       Something you would consider in making  
16       your decisions about which filter to use?

17                   MS. HELM: Object to the form.

18           A       If it -- yes.

19           Q       And is that something that you would  
20       pass on to your patients?

21           A       I wouldn't use the filter if I was  
22       aware that deaths were occurring concurrently with  
23       me placing these filters.

24           Q       Okay. Are you aware that -- that  
25       perforation is progressive in nature?

Do Not Disclose - Subject to Further Confidentiality Review

1 accounts, yes.

2 MS. HELM: Object to the form.

3 A And so what was the question?

4 Q I'll withdraw it.

5 We were talking earlier about sales  
6 representatives being present when you were doing  
7 IVC placements in bariatric patients. Do you  
8 remember that?

9 A Yes.

10 Q Did you ever have any specific  
11 discussions with those reps about the use of IVC  
12 filters in bariatric patients?

13 A I don't recall.

14 Q Okay. Do you remember ever being told  
15 by any Bard sales representative that IVC filters  
16 should not be used in bariatric patients?

17 A No.

18 Q Would you expect the -- the information  
19 that a -- that a medical device sales rep was --  
20 was providing to you to be honest, accurate and  
21 complete?

22 A Yes.

23 Q And would the same be true of a medical  
24 device company in general?

25 A Yes.

Do Not Disclose - Subject to Further Confidentiality Review

1 product?

2 A Yes.

3 Q And something that you would use when  
4 meeting with patients?

5 A Yes.

6 Q If there were problems with one of  
7 Bard's IVC filters such as the Eclipse for  
8 example, would you have expected the Bard sales  
9 rep to inform you of those problems?

10 MS. HELM: Object to the form.

11 A Yes.

12 Q And were you ever told by any Bard  
13 sales representative about problems with the  
14 Eclipse filter?

15 MS. HELM: Object to the form.

16 A No.

17 Q Were you ever told by any Bard sales  
18 representative about any -- any problems or  
19 complications associated with any of their  
20 filters?

21 MS. HELM: Object to the form.

22 A No.

23 Q Sir, let's go through some of your  
24 records, and I'm going to try to -- I tried to  
25 find the earliest I could find.

Do Not Disclose - Subject to Further Confidentiality Review

[REDACTED]

[REDACTED]

[REDACTED]

4 Did I read that correctly?

5 A Yes.

6 Q [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

25 A Yes.



Do Not Disclose - Subject to Further Confidentiality Review

■ [REDACTED] ■ [REDACTED]

■ [REDACTED]

3 A Yes.

4 Q And what is the proximal duodenum?

5 A There's four parts to the duodenum.

6 The proximal duodenum is the first part.

7 Q Okay. Am I saying it correct or wrong  
8 when I say duodenum?

9 A It depends on what country you're from.

10 Q Okay. What country says is that way?

11 A England.

12 Q So how should I be saying it?

13 A Duodenum.

14 Q That's what I used to say but then --

15 MR. O'CONNOR: I told you.

16 Q -- everybody else said duodenum. So I  
17 should go with duodenum?

18 A In America it's normally duodenum.

19 Q Perfect. I am definitely from America.

20 All right. So looking at Page 13, this

21 appears to be a [REDACTED] [REDACTED] [REDACTED]

■ [REDACTED] is that correct?

23 A Yes.

24 Q [REDACTED]

25 [REDACTED]

Do Not Disclose - Subject to Further Confidentiality Review

1 [REDACTED] [REDACTED] [REDACTED]

2 A Yes.

3 Q And then [REDACTED] [REDACTED] [REDACTED]

4 [REDACTED] [REDACTED]

5 A Yes.

6 Q [REDACTED] [REDACTED]

7 [REDACTED]

8 MS. HELM: Object to the form.

9 A [REDACTED]

10 [REDACTED]

11 [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

12 [REDACTED]

13 [REDACTED] [REDACTED]

14 Q Okay. And then looking at -- at plan  
15 on that page it says, [REDACTED]

16 [REDACTED]

17 [REDACTED] Procedure

18 and risks" --

19 I guess did I read that first sentence  
20 correctly?

21 A Yes.

22 Q And then you went on to say, [REDACTED]

23 [REDACTED]

24 [REDACTED] [REDACTED] [REDACTED]

25 [REDACTED] [REDACTED]

Do Not Disclose - Subject to Further Confidentiality Review

1 [REDACTED]

2 [REDACTED]

3 [REDACTED] [REDACTED]

4 [REDACTED]

5 A What's typed right there.

6 [REDACTED] [REDACTED] [REDACTED]

7 [REDACTED]

8 A What is right there.

9 Q [REDACTED] [REDACTED] [REDACTED]

10 [REDACTED] [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED] [REDACTED]

15 [REDACTED] [REDACTED]

16 [REDACTED] [REDACTED]

17 [REDACTED] [REDACTED]

18 [REDACTED] [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED] [REDACTED]

22 [REDACTED] [REDACTED] [REDACTED]

23 [REDACTED] [REDACTED] [REDACTED]

24 [REDACTED] on [REDACTED]

25 [REDACTED] All right. Well --

1 MS. HELM: Object to the form.

3

1



■

■

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

| Year | 2000 | 2001 | 2002 | 2003 |
|------|------|------|------|------|
| 1    | 100  | 100  | 100  | 100  |
| 2    | 100  | 100  | 100  | 100  |
| 3    | 100  | 100  | 100  | 100  |
| 4    | 100  | 100  | 100  | 100  |
| 5    | 100  | 100  | 100  | 100  |
| 6    | 100  | 100  | 100  | 100  |
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| 8    | 100  | 100  | 100  | 100  |
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| 21   | 100  | 100  | 100  | 100  |
| 22   | 100  | 100  | 100  | 100  |
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| 24   | 100  | 100  | 100  | 100  |
| 25   | 100  | 100  | 100  | 100  |
| 26   | 100  | 100  | 100  | 100  |
| 27   | 100  | 100  | 100  | 100  |
| 28   | 100  | 100  | 100  | 100  |
| 29   | 100  | 100  | 100  | 100  |
| 30   | 100  | 100  | 100  | 100  |
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| 54   | 100  | 100  | 100  | 100  |
| 55   | 100  | 100  | 100  | 100  |
| 56   | 100  | 100  | 100  | 100  |
| 57   | 100  | 100  | 100  | 100  |
| 58   | 100  | 100  | 100  | 100  |
| 59   | 100  | 100  | 100  | 100  |
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| 62   | 100  | 100  | 100  | 100  |
| 63   | 100  | 100  | 100  | 100  |
| 64   | 100  | 100  | 100  | 100  |
| 65   | 100  | 100  | 100  | 100  |
| 66   | 100  | 100  | 100  | 100  |
| 67   | 100  | 100  | 100  | 100  |
| 68   | 100  | 100  | 100  | 100  |
| 69   | 100  | 100  | 100  | 100  |
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| 77   | 100  | 100  | 100  | 100  |
| 78   | 100  | 100  | 100  | 100  |
| 79   | 100  | 100  | 100  | 100  |
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§ 87(2)(b) § 87(2)(b) -- § 87(2)(b)

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■ ■ ■

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|---|---|---|
| 1 | 2 | 3 |
|---|---|---|

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Do Not Disclose - Subject to Further Confidentiality Review

[REDACTED]

9 A Well --

10 MS. HELM: Object to the form.

11 A -- if I can go back to the last  
12 question, I mean I -- I see what's here. But many  
13 times I relate that if it couldn't be retrieved --  
14 [REDACTED] But if it  
15 couldn't be retrieved, but prior to that they were  
16 all permanent anyway.

17 Q Okay. [REDACTED]

18 [REDACTED]

19 A No.

20 Q And -- and so did -- I guess my  
21 question is: [REDACTED]

22 [REDACTED]  
23 [REDACTED]

24 MS. HELM: Object to the form.

25 A In what's documented here, yes.

Do Not Disclose - Subject to Further Confidentiality Review

1 Q [REDACTED] [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
9 MS. HELM: Object to the form.  
10 [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
16 MS. HELM: Object to the form.  
[REDACTED]  
[REDACTED]  
19 MS. HELM: Object to the form.  
20 [REDACTED]  
21 Q And did you ever --  
22 A [REDACTED]  
[REDACTED]  
24 [REDACTED]  
25 [REDACTED]

Do Not Disclose - Subject to Further Confidentiality Review

1 [REDACTED]

2 MS. HELM: Object to the form.

3 A [REDACTED]

4 Q [REDACTED]

5 [REDACTED] -- [REDACTED]

6 [REDACTED] -- [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 MS. HELM: Object to the --

13 Q -- is that correct?

14 MS. HELM: Object to the form.

15 A [REDACTED] [REDACTED] [REDACTED]

16 [REDACTED]

17 Q I do. And we'll -- we'll talk about

18 that.

19 But isn't the -- would the consent form

20 essentially have the same -- is it essentially a

21 statement of -- of what you discussed [REDACTED]

22 A Yes.

23 MS. HELM: Object to the form.

24 Q Would there be things in the consent

25 form that would be different than what you've

Do Not Disclose - Subject to Further Confidentiality Review

1 listed here?

2 A No.

3 Q [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 A What is there, an FDA statement had  
9 come out shortly prior to this that we began to  
10 inform the patients that the FDA said it should be  
11 removed.

12 Q Are you talking about the July 2010 FDA  
13 statement?

14 A Are there others?

15 Q (Laughter). Do you remember  
16 specifically when they --

17 A No.

18 Q Okay. And what did the FDA say about  
19 removal of IVC filters?

20 A They should be retrieved if possible.

21 Q And why?

22 MS. HELM: Object to the form.

23 A I don't recall.

24 Q [REDACTED]

[REDACTED]



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1 And so this was a record from  
2 April 11th of 2012; is that correct?

3 A Yes.

4 MS. HELM: Exactly five days ago today.

5 MR. DeGREEFF: Hey, you were married  
6 exactly --

7 MS. HELM: 25 years ago today.

8 MR. DeGREEFF: That's right. Happy  
9 anniversary by the way.

10 MS. HELM: Where is my bottle of  
11 champagne?

12 MR. DeGREEFF: I know who would you  
13 rather be with?

14 MS. HELM: On the advice of counsel I  
15 decline to answer.

16 MR. DeGREEFF: There you go. All  
17 right. I'm sure I'm super high on that list.

18 BY MR. DeGREEFF:

19 Q So -- so in -- in deciding which --  
20 which filter to use, do you rely on information  
21 from the manufacturer?

22 A No.

23 Q Okay. [REDACTED]

[REDACTED] [REDACTED] [REDACTED]

25 A That's what I'm looking for.

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1 A Okay.

2 Q All right. You state that the risks --  
3 under indications and findings it says, "The risks  
4 and benefits were discussed with the patient and  
5 consent was obtained."

6 Did I read that correctly?

7 A Yes.

8 Q [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 Q And is this -- is this consent that was  
13 obtained, is that a reference to the consent  
14 document?

15 A Yes.

16 MR. DeGREEFF: 9?

17 COURT REPORTER: Yes.

18 MR. DeGREEFF: Thank you, ma'am.

19 (DEPOSITION EXHIBIT 9 WAS MARKED.)

20 BY MR. DeGREEFF:

21 Q I'm handing you what's been marked as  
22 Deposition Exhibit 9. [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 A Yes.

1 Q And if you'll look at the -- and this  
2 is a consent -- this is titled 'Consent to  
3 Operation or Other Procedures', correct?

5           Q       So is this a consent to the  
6       complications -- potential complications  
7       associated with the -- with the actual procedure  
8       for implantation?

[illegible]

| Age Group | Percentage Vaccinated |
|-----------|-----------------------|
| 18-24     | 15%                   |
| 25-34     | 85%                   |
| 35-44     | 75%                   |
| 45-54     | 65%                   |
| 55-64     | 55%                   |
| 65-74     | 45%                   |
| 75-84     | 35%                   |
| 85+       | 25%                   |

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1 [REDACTED]

2 [REDACTED]

3 [REDACTED] [REDACTED]

4 Q Okay. You wouldn't have -- I guess  
5 strike that.

6 Would you have implanted it if there  
7 was any indication of damage or a problem with the  
8 filter?

9 A No.

10 Q [REDACTED]

11 [REDACTED]

12 [REDACTED] [REDACTED]

13 Q Is it fair to say that you -- strike  
14 that.

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 MS. HELM: Object to the form.

19 [REDACTED] [REDACTED]

20 [REDACTED] [REDACTED]

21 [REDACTED]

22 MS. HELM: Object to the form.

23 [REDACTED] [REDACTED]

24 [REDACTED]

25 [REDACTED] [REDACTED] [REDACTED]

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1 f [REDACTED]  
2 [REDACTED]  
3 A No.  
4 MS. HELM: Object to the form.  
5 [REDACTED]  
6 [REDACTED]  
7 MS. HELM: Object to the form.  
8 [REDACTED] [REDACTED] [REDACTED]  
9 [REDACTED] [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 MS. HELM: Object to the form.  
13 [REDACTED]  
14 [REDACTED] [REDACTED]  
15 Q No, okay, strike that. No, that's not  
16 what I meant.  
17 [REDACTED] [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED] [REDACTED]  
21 MS. HELM: Object to the form.  
22 [REDACTED]  
23 [REDACTED] [REDACTED]  
24 [REDACTED]  
25 [REDACTED] [REDACTED]

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1 Q Would you -- if you expected those --  
2 those issues to occur, would you have used the  
3 filter?

4 MS. HELM: Object to the form.

5 A No.

6 Q And is it -- in your opinion is it  
7 reasonable for a patient to expect those  
8 complications not to occur?

9 MS. HELM: Object to the form.

10 A Unfortunately there's complications  
11 with any product.

12 Q Well, if -- if a patient is not  
13 informed of those complications, they can't  
14 reasonably make a decision whether -- strike that.  
15 Move on.

16 The IVC filter complications can occur  
17 even if -- even if the implanting physician does  
18 everything correctly; is that correct?

19 MS. HELM: Object to the form.

20 A Yes.

21 Q Doctor, would you agree that a -- that  
22 a perforation of the vena cava filter is -- is not  
23 within a patient's reasonable expectations?

24 MS. HELM: Object to the form.

25 A The perforation of the vena cava

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1           Q       Strike that. Let me see if I can say  
2       that a better way.

3                   Is it reasonable for a -- for a patient  
4       to expect a vena cava filter not to penetrate its  
5       -- their vena cava?

6                   MS. HELM: Object to the form.

7           A       It's reasonable that they wouldn't  
8       expect that, yes.

9           Q       Okay. And would it -- is it reasonable  
10      for a patient to expect an IVC filter not to  
11      penetrate their organs?

12                  MS. HELM: Object to the form.

13          A       That is what they should expect.

14          Q       In your -- and in your experience would  
15      it be a rare and unusual circumstance where a vena  
16      cava filter would perforate a patient's organs?

17                  MS. HELM: Object to the form.

18          A       Yes.

19          Q       That's not something that you would  
20      expect to occur, correct?

21                  MS. HELM: Object to the form.

22          A       It's certainly within the realm of  
23      small risks.

24          Q       Is it -- when you're putting a filter  
25      into a patient, that's not something you would

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1 expect to occur; is that fair?

2 MS. HELM: Object to the form.

3 A It's something that can occur, but it's  
4 not something I would expect to occur.

5 Q Okay. Doctor, what is -- that would  
6 not be within your reasonable expectation of an  
7 outcome from a -- from a future implantation -- of  
8 a future outcome from an implanted IVC filter,  
9 fair?

10 MS. HELM: Object to the form.

11 A It would be a possible but not likely  
12 outcome.

13 Q Okay. Doctor, are you -- do you know  
14 what an IFU is?

15 A I have heard but I've forgotten.

16 Q Are you familiar with the instructions  
17 for use for vena cava filters?

18 A Yes.

19 (DEPOSITION EXHIBIT 10 WAS MARKED.)

20 Q I'm handing you what's been marked as  
21 Exhibit 10. Have you seen the instructions for  
22 use for the Eclipse filter before?

23 A Yes.

24 MS. HELM: Are you representing that  
25 this is the IFU filter at issue?



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1 to be contraindicated for something?

2 A Those are the situations in which it's  
3 not advisable to place it.

4 Q If a -- if a -- if something was listed  
5 as a contraindication for use in the IFU, would  
6 you implant the filter in -- in those situations?

7 A No.

8 Q Contraindications for use does not  
9 include bariatric surgery, does it?

10 A No.

11 Q If -- if contraindications for use in  
12 the Eclipse IFU had listed bariatric surgery,  
13 would you use the filter in bariatric patients?

14 A No.

15 Q Do you review the IFU for medical  
16 devices that you use?

17 A I have seen this. I don't know that  
18 I've read every word in it.

19 Q Okay. Is it your practice, though, to  
20 review the IFU for devices that you're implanting  
21 into your patients?

22 A If it's a new device, I would look it  
23 over.

24 Q And is -- and part of the reason you  
25 review an IFU is so that you can properly inform

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1 patients; is that correct?

2 MS. HELM: Object to the form.

3 A No.

4 Q You wouldn't -- you wouldn't inform  
5 patients of warnings that are listed in an IFU?

6 A If they were pertinent.

7 Q Okay. If the IFU included pertinent  
8 warnings, is that something that you would pass on  
9 to your patients?

10 A Yes.

11 Q I want you to look at the -- at the  
12 warnings section. If you look on it's Page 881.  
13 12 says, "Movement" --

14 A Which 12, the upper?

15 Q The upper --

16 A The top 12?

17 Q The upper 12, sorry, under the warnings  
18 sections it says, "Movement, migration or tilt of  
19 the filter are known complications of vena cava  
20 filters.

21 Migration of the filters to the heart  
22 or lungs has been reported. There have also been  
23 reports of the caudal migration of the filter."

24 Did I read that correctly?

25 A Yes.

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1 Q This section -- strike that.

2 Does this make any differentiation  
3 between Bard filters and competitor filters?

4 A I don't know.

5 Q Would you read it to make any  
6 differentiation between Bard filters and  
7 competitor filters?

8 MS. HELM: Object to the form.

9 A Would I read what?

10 Q The language we just talked about.  
11 "Movement, migration or tilt of the filter are  
12 known complications of vena cava filters."

13 That's discussing all vena cava  
14 filters, correct?

15 MS. HELM: Object to the form.

16 A That's how I would read it, yes.

17 Q Is there anything about that statement  
18 that informs you of an increased risk of movement,  
19 migration or tilt with Bard filters versus  
20 competitor filters?

21 A No.

22 Q Is there anything about that statement  
23 that warns you of an increased risk of movement,  
24 migration or tilt with Bard filters versus -- Bard  
25 optional filters versus Bard's permanent filters?

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1 MS. HELM: Object to the form.

2 A No.

3 Q There's -- is there anything that would  
4 -- about that language that would lead you as a  
5 physician to believe that the Eclipse had a higher  
6 risk of movement, migration or tilt than any other  
7 filter?

8 MS. HELM: Object to the form.

9 A No.

10 Q If the -- if the Bard filter, the  
11 Eclipse, had an increased risk of migration over  
12 other filters, is that something you would want to  
13 know?

14 MS. HELM: Object to the form.

15 A Yes.

16 Q Is that something you would take into  
17 account in your risk benefit analysis on whether  
18 to use the filter?

19 A Yes.

20 Q Would it effect your prescribing  
21 habits?

22 A Yes.

23 Q Is it something you would pass on to  
24 the patient?

25 A If it's a significant difference, I

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1 wouldn't use the filter.

2 Q Doctor, as a -- as a physician, would  
3 you want to use the safest available IVC filter  
4 that would establish the goal of stopping PEs?

5 MS. HELM: Object to the form.

6 A Yes.

7 Q And, Doctor, just below that there's  
8 a -- in bold it says, "See potential complications  
9 section for further information regarding other  
10 known filter complications."

11 Did I read that correctly?

12 A I don't see that.

13 Q It's the bold right below No. 14.

14 MS. HELM: My copy is so bad you can't  
15 tell that it's bolded.

16 A Yeah, I don't know that it's bold.  
17 Yeah, I see what you're saying.

18 Q And it says, "See potential  
19 complications section for" -- and for the record  
20 this is how it was produced to us, so there's not  
21 a lot we can do about it.

22 And it says, "See potential  
23 complications for further information regarding  
24 other known filters complications."

25 Did I read that correctly?

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[REDACTED]

9 A [REDACTED]

10 Q Okay. And when a -- when a filter  
11 becomes embedded and irretrievable, the patient  
12 continues to have the risk of tilt -- I mean the  
13 risk of perforation of the filter, correct?

14 MS. HELM: Object to the form.

15 A I'm not an expert on the long-term  
16 consequences of filters.

17 Q Okay. So as you sit here, you're not  
18 -- you're not -- you don't consider yourself an  
19 expert on any long-term complications of filters?

20 A No.

21 Q Okay. Have you spoken to the  
22 interventional radiologist who tried to remove the  
23 filter?

24 A Not that I'm aware of.

25 MR. DeGREEFF: Go ahead. No, wait. I

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1 penetration of the IVC filter into the duodenum  
2 could cause chronic abdominal pain?

3 MS. HELM: Object to the form.

4 A Perforated intraluminally into the  
5 duodenum?

6 Q Yes.

7 A Potentially.

8 Q What about tenderness of the abdomen?

9 A If the vena cava filter were visible  
10 within the lumen of the duodenum, then it may  
11 cause some ulceration.

12 Q Which would leave the tenderness of the  
13 abdomen?

14 A Yes.

15 Q And what about abdominal cramping?

16 A Yes.

17 Q What about nausea?

18 A Well, your -- yes.

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

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1

2

3

A

4

MR. DeGREEFF: Go ahead.

5

DIRECT EXAMINATION

6

BY MR. O'CONNOR:

7

Q

All right. Doctor, I'm Mark O'Connor

8

and I'm another lawyer representing the Plaintiff

9

in this matter. I have some additional questions.

10

I've sat here and listened to you and

11

it sounds to me as though you are a medical doctor

12

who places your patients' interest and safety and

13

their well-being as a No. 1 priority; is that

14

fair?

15

MS. HELM: Object to the form.

16

A

That and having a outcome, yes.

17

Q

And is it fair to say, Doctor, that you

18

would expect that a medical device manufacturer

19

would similarly place a patient's interest and

20

safety first as a priority when it is promoting a

21

medical device?

22

MS. HELM: Object to the form.

23

A

Sometimes there are risks to devices

24

but...

25

Q

As a general rule, though, is it your



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1 I'm not a marketing expert. I don't know --

2 Q Setting marketing aside, if Bard was  
3 aware that there were rates of complications  
4 stemming from caudal migration in the Eclipse  
5 filter, I think we've agreed that that's something  
6 you would have expected them to tell you?

7 MS. HELM: Object to the form.

8 A Yes.

9 Q And told you as soon they knew, right?

10 MS. HELM: Object to the form.

11 A As soon as they verified there was a  
12 significant issue.

13 Q And if they were receiving feedback  
14 from other doctors that there were problems in the  
15 Eclipse with caudal migration as early as 2010, is  
16 that something you also would have expect to  
17 notify you as a doctor who was using the Eclipse?

18 MS. HELM: Object to the form.

19 A I -- I wouldn't expect that from A  
20 marketing standpoint. I would assume they would  
21 improve the filter.

22 Q Well, you would expect Bard to provide  
23 you with accurate and through information as it  
24 became aware of problems with the filter, right?

25 A Yes.

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1 A Yes.

2 Q If Bard was aware that there were  
3 problems with the designs of a filter that was on  
4 the market that was causing complications and  
5 problems with patients, would you expect Bard to  
6 notify you about that immediately?

7 MS. HELM: Object to the form.

8 A Yes.

9 Q And would you expect Bard to notify you  
10 immediately if it was in the process of  
11 redesigning the filter in a manner to reduce or  
12 avoid the complications?

13 MS. HELM: Object to the form.

14 A Yes.

15 Q Because that information would help you  
16 decide whether you even wanted to use the filter  
17 in the first place, true?

18 A Yes.

19 MS. HELM: Object to the form.

20 Q Did you have an understanding, Doctor,  
21 you -- you had the Eclipse filter. Did you have  
22 an understanding that there were filters that were  
23 launched by Bard that were predecessors to the  
24 Eclipse filter?

25 A Was I aware there were predecessors?

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1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED] [REDACTED]  
4 [REDACTED] [REDACTED] [REDACTED] -- [REDACTED]  
5 [REDACTED] -- [REDACTED]  
6 [REDACTED] [REDACTED] [REDACTED]  
7 [REDACTED] [REDACTED]  
8 [REDACTED] [REDACTED] [REDACTED]  
9 [REDACTED]  
10 [REDACTED] [REDACTED]

11 Q Okay. If you would turn the page of  
12 this IFU, which marked I've as Exhibit 17, and on  
13 the next page under G you see where it says,  
14 "Potential complications"?

15 A Yes.

16 Q And it says, "Possible complications  
17 include but are not limited to the following." Do  
18 you see where I am?

19 A Yes.

20 Q And again -- again they tell you  
21 "Movement, migration or tilt the filter are known  
22 complications of vena cava filters," correct?

23 A Yes.

24 Q And they also tell you that "Migration  
25 of filters to the heart or lungs have been

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1 intervention."

2 Did I read that correctly?

3 A Yes.

4 Q At the time [REDACTED] [REDACTED]

5 [REDACTED] Bard told you -- had  
6 told you that there had -- that complications  
7 could result in medical intervention and/or death,  
8 correct?

9 A They provided me with this literature.

10 Q Yes, they provided you with  
11 information.

12 A Yes.

13 Q And they told you that there had been  
14 reports of complications including death  
15 associated with the use of IVC filters in morbidly  
16 patients, correct?

17 A They provided me with literature that  
18 stated that, yes.

19 Q Yes, okay. And they provided you with  
20 literature that stated you needed to take that  
21 into consideration when doing your risk-benefit  
22 analysis [REDACTED]

23 [REDACTED] [REDACTED] [REDACTED]

24 A Yes.

25 Q Okay. And this information was

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1 available to you when you made that risk-benefit  
2 analysis?

3 A Yes.

4 Q Okay. Today you were shown a number of  
5 internal documents from Bard. Do you recall  
6 those?

7 A Yes.

8 Q Some e-mails and some other internal  
9 documents. Do you recall those?

10 A Yes.

11 Q During the course of your practice, has  
12 any medical device company ever shown you their  
13 internal documents?

14 A No.

15 Q During the course of your practice, has  
16 any internal -- any medical device company ever  
17 shown you a draft e-mail?

18 A No.

19 Q Okay. It is important to you to have  
20 reliable information when making a risk-benefit  
21 analysis on whether to use a medical device. Do  
22 you agree with me on that?

23 A Yes.

24 Q Okay. As you sit here today, you don't  
25 know the context of any of these internal Bard

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1           Q       Doctor, a Bard representative sat with  
2       you and helped you place filters in bariatric  
3       surgery patient, correct?

4           A       He --

5                   MS. HELM: Object to the form.

6           A       He was present.

7           Q       He was present while you were doing it?

8           A       Yes.

9           Q       And why did you want him there? Why  
10       did you -- why was he is present? What was the  
11       purpose of him being there?

12          A       To provide information if I had  
13       questions.

14          Q       Okay. To help you if you needed it?

15          A       To provide information. He wouldn't  
16       physically help me.

17          Q       At any point did he tell you, hey, you  
18       shouldn't use that IVC filter with bariatric  
19       patients?

20          A       Not that I recall.

21          Q       If -- if there was some concern within  
22       Bard about -- about using IVC filters with -- with  
23       bariatric patients, would you have expected him to  
24       tell you that?

25                   MS. HELM: Object to the form.

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1 filter --

2 A Yes.

3 Q -- you did not have all the -- based on  
4 the documents you've seen here today, there are  
5 things that Bard didn't tell you about risks and  
6 problems with its filters, fair?

7 MS. HELM: Object to the form.

8 A Yes.

9 Q Now, Doctor, your care and treatment  
10 with regard to the filters was to implant the  
11 filters, fair?

12 A Yes.

13 Q You didn't do explants of the filters?

14 A No.

15 Q You didn't -- you didn't CT scan  
16 filters and check for complications?

17 A No.

18 Q So when it comes to complications that  
19 your patients may or may not have had, the  
20 person -- you may not be the right person to talk  
21 to; is that fair?

22 A If they return for follow-up, then I  
23 would think that they would make me aware.

24 Q And we talked about the fact that --  
25 that eventually as many as 85 percent stop

**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit M-D - REDACTED**





Deposition of:  
**Debra Mulkey**

*February 8, 2017*

In the Matter of:  
**In Re: Bard IVC Filters Products  
Liability**

Veritext Legal Solutions  
1075 Peachtree St. NE , Suite 3625  
Atlanta, GA, 30309  
800.808.4958 | [calendar-atl@veritext.com](mailto:calendar-atl@veritext.com) | 770.343.9696

Debra Mulkey  
In Re: Bard IVC Filters Products Liability

February 8, 2017

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1 toll-free number is attorney-client privilege?

2 MR. DEGREEFF: To an attorney law firm, yeah.

3 MS. HELM: Okay. Before you retain them, okay.

4 BY MS. HELM:

5 Q Do you know how you got to Mr. Degreeff's  
6 firm?

7 A I was transferred.

8 Q Was your call physically transferred to his  
9 firm, or did you have to hang up and call back?

10 A No. Neither.

11 Q Okay. Did someone from Mr. Degreeff's firm  
12 call you?

13 A I received a letter.

14 Q And without the -- I don't want to know the  
15 contents of the letter.

16 A I couldn't tell you anyway.

17 Q Okay. From whom did you receive a letter,  
18 someone in Mr. Degreeff's firm?

19 A The firm, yes.

20 Q Mr. Degreeff's law firm?

21 A Yes.

22 Q Okay. You -- I'm not going to go into the  
23 substance, but I'm entitled to know the event. You saw  
24 an ad in the fall of 2015; is that right?

25 A Yes.

Debra Mulkey  
In Re: Bard IVC Filters Products Liability

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1 Q And it was an ad about IVC filters; is that  
2 right?

3 A Yes.

4 Q And the ad said if you have an IVC filter, you  
5 may be entitled to compensation, call this number; is  
6 that right?

7 MR. DEGREEFF: Object to form.

8 Q Generally?

9 A Generally.

10 Q Okay. You called the toll-free number, you  
11 spoke to someone, and then without going into the  
12 substance of the conversation, the next event was you  
13 received a letter from Mr. Degreeff's firm; is that  
14 right?

15 A Correct.

16 Q Okay. Have you signed an agreement or a  
17 contract of some kind with Mr. Degreeff's law firm?

18 MR. DEGREEFF: If you know.

19 A I'm not -- I'm not sure.

20 Q Okay. When did Mr. Degreeff or his law firm  
21 become your lawyers?

22 MR. DEGREEFF: Object to the form.

23 A Shortly after -- after calling the number. I'm  
24 not certain of the date.

25 Q I think in your information you provided to us

Debra Mulkey  
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1 you -- you're welcome to look and correct me. It's on  
2 page 2 of Exhibit 2, the big one. And on page 2 under  
3 paragraph 1E, it says you first retained a lawyer on  
4 October 14, 2015. Does that sound right?

5 A That does.

6 Q Okay. So you saw the ad sometime before  
7 October 14, 2015; is that right?

8 A Just a matter of a week or so, yes.

9 Q Okay. Saw the ad, you made the phone call,  
10 and subsequently got a -- at least got a letter from Mr.  
11 Degreeff's firm; is that right?

12 A Correct.

13 Q Okay. Okay. Other than that one phone call,  
14 the one toll-free number from the ad you saw, did you  
15 reach out to any other lawyers or law firms?

16 A No.

17 Q Okay. And did you make the call after --  
18 after you saw the ad for the very first time?

19 A No.

20 Q Okay. You had seen the ad more than once?

21 A Yes.

22 Q Or had you seen more than one ad?

23 A I don't believe I saw more than one ad.

24 Q Okay. And when did you first start seeing the  
25 ads?

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|   |   |                |
|---|---|----------------|
| 2 | A | Dr. Thompkins. |
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5 A I'm not certain exact.

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| Country | Year | Value |
|---------|------|-------|
| Algeria | 2000 | 0.00  |
| Algeria | 2001 | 0.00  |
| Algeria | 2002 | 0.00  |
| Algeria | 2003 | 0.00  |
| Algeria | 2004 | 0.00  |
| Algeria | 2005 | 0.00  |
| Algeria | 2006 | 0.00  |
| Algeria | 2007 | 0.00  |
| Algeria | 2008 | 0.00  |
| Algeria | 2009 | 0.00  |
| Algeria | 2010 | 0.00  |
| Algeria | 2011 | 0.00  |
| Algeria | 2012 | 0.00  |
| Algeria | 2013 | 0.00  |
| Algeria | 2014 | 0.00  |
| Algeria | 2015 | 0.00  |
| Algeria | 2016 | 0.00  |
| Algeria | 2017 | 0.00  |
| Algeria | 2018 | 0.00  |
| Algeria | 2019 | 0.00  |
| Algeria | 2020 | 0.00  |
| Algeria | 2021 | 0.00  |
| Algeria | 2022 | 0.00  |
| Algeria | 2023 | 0.00  |
| Algeria | 2024 | 0.00  |
| Algeria | 2025 | 0.00  |
| Algeria | 2026 | 0.00  |
| Algeria | 2027 | 0.00  |
| Algeria | 2028 | 0.00  |
| Algeria | 2029 | 0.00  |
| Algeria | 2030 | 0.00  |
| Algeria | 2031 | 0.00  |
| Algeria | 2032 | 0.00  |
| Algeria | 2033 | 0.00  |
| Algeria | 2034 | 0.00  |
| Algeria | 2035 | 0.00  |
| Algeria | 2036 | 0.00  |
| Algeria | 2037 | 0.00  |
| Algeria | 2038 | 0.00  |
| Algeria | 2039 | 0.00  |
| Algeria | 2040 | 0.00  |
| Algeria | 2041 | 0.00  |
| Algeria | 2042 | 0.00  |
| Algeria | 2043 | 0.00  |
| Algeria | 2044 | 0.00  |
| Algeria | 2045 | 0.00  |
| Algeria | 2046 | 0.00  |
| Algeria | 2047 | 0.00  |
| Algeria | 2048 | 0.00  |
| Algeria | 2049 | 0.00  |
| Algeria | 2050 | 0.00  |
| Algeria | 2051 | 0.00  |
| Algeria | 2052 | 0.00  |
| Algeria | 2053 | 0.00  |
| Algeria | 2054 | 0.00  |
| Algeria | 2055 | 0.00  |
| Algeria | 2056 | 0.00  |
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| Algeria | 2062 | 0.00  |
| Algeria | 2063 | 0.00  |
| Algeria | 2064 | 0.00  |
| Algeria | 2065 | 0.00  |
| Algeria | 2066 | 0.00  |
| Algeria | 2067 | 0.00  |
| Algeria | 2068 | 0.00  |
| Algeria | 2069 | 0.00  |
| Algeria | 2070 | 0.00  |
| Algeria | 2071 | 0.00  |
| Algeria | 2072 | 0.00  |
| Algeria | 2073 | 0.00  |
| Algeria | 2074 | 0.00  |
| Algeria | 2075 | 0.00  |
| Algeria | 2076 | 0.00  |
| Algeria | 2077 | 0.00  |
| Algeria | 2078 | 0.00  |
| Algeria | 2079 | 0.00  |
| Algeria | 2080 | 0.00  |
| Algeria | 2081 | 0.00  |
| Algeria | 2082 | 0.00  |
| Algeria | 2083 | 0.00  |
| Algeria | 2084 | 0.00  |
| Algeria | 2085 | 0.00  |
| Algeria | 2086 | 0.00  |
| Algeria | 2087 | 0.00  |
| Algeria | 2088 | 0.00  |
| Algeria | 2089 | 0.00  |
| Algeria | 2090 | 0.00  |
| Algeria | 2091 | 0.00  |
| Algeria | 2092 | 0.00  |
| Algeria | 2093 | 0.00  |
| Algeria | 2094 | 0.00  |
| Algeria | 2095 | 0.00  |
| Algeria | 2096 | 0.00  |
| Algeria | 2097 | 0.00  |
| Algeria | 2098 | 0.00  |
| Algeria | 2099 | 0.00  |
| Algeria | 2100 | 0.00  |
| Algeria | 2101 | 0.00  |
| Algeria | 2102 | 0.00  |
| Algeria | 2103 | 0.00  |
| Algeria | 2104 | 0.00  |
| Algeria | 2105 | 0.00  |
| Algeria | 2106 | 0.00  |
| Algeria | 2107 | 0.00  |
| Algeria | 2108 | 0.00  |
| Algeria | 2109 | 0.00  |
| Algeria | 2110 | 0.00  |
| Algeria | 2111 | 0.00  |
| Algeria | 2112 |       |

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1. **Introduction**

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| Year | Country | Population (millions) | Urban population (millions) | Urban population (%) |
|------|---------|-----------------------|-----------------------------|----------------------|
| 1980 | China   | 959                   | 190                         | 19.8                 |
| 1985 | China   | 1059                  | 220                         | 20.8                 |
| 1990 | China   | 1154                  | 250                         | 21.7                 |
| 1995 | China   | 1236                  | 290                         | 23.5                 |
| 2000 | China   | 1267                  | 330                         | 26.0                 |
| 2005 | China   | 1328                  | 370                         | 27.8                 |
| 2010 | China   | 1371                  | 410                         | 29.9                 |
| 2015 | China   | 1404                  | 450                         | 32.1                 |
| 2020 | China   | 1437                  | 490                         | 34.1                 |
| 2025 | China   | 1469                  | 530                         | 36.1                 |
| 2030 | China   | 1500                  | 570                         | 38.0                 |
| 2035 | China   | 1530                  | 610                         | 40.0                 |
| 2040 | China   | 1559                  | 650                         | 41.7                 |
| 2045 | China   | 1587                  | 690                         | 43.5                 |
| 2050 | China   | 1614                  | 730                         | 45.2                 |
| 2060 | China   | 1640                  | 770                         | 46.9                 |
| 2070 | China   | 1665                  | 810                         | 48.7                 |
| 2080 | China   | 1689                  | 850                         | 50.3                 |
| 2090 | China   | 1712                  | 890                         | 51.9                 |
| 2100 | China   | 1734                  | 930                         | 53.6                 |
| 1980 | India   | 686                   | 100                         | 14.6                 |
| 1985 | India   | 752                   | 120                         | 16.0                 |
| 1990 | India   | 819                   | 140                         | 17.1                 |
| 1995 | India   | 885                   | 160                         | 18.1                 |
| 2000 | India   | 951                   | 180                         | 18.9                 |
| 2005 | India   | 1016                  | 200                         | 19.7                 |
| 2010 | India   | 1080                  | 220                         | 20.4                 |
| 2015 | India   | 1143                  | 240                         | 21.0                 |
| 2020 | India   | 1205                  | 260                         | 21.6                 |
| 2025 | India   | 1266                  | 280                         | 22.1                 |
| 2030 | India   | 1326                  | 300                         | 22.6                 |
| 2035 | India   | 1385                  | 320                         | 23.1                 |
| 2040 | India   | 1443                  | 340                         | 23.6                 |
| 2045 | India   | 1500                  | 360                         | 24.0                 |
| 2050 | India   | 1556                  | 380                         | 24.4                 |
| 2060 | India   | 1611                  | 400                         | 24.8                 |
| 2070 | India   | 1665                  | 420                         | 25.2                 |
| 2080 | India   | 1718                  | 440                         | 25.6                 |
| 2090 | India   | 1770                  | 460                         | 25.9                 |
| 2100 | India   | 1821                  | 480                         | 26.4                 |
| 1980 | USA     | 226                   | 180                         | 79.7                 |
| 1985 | USA     | 233                   | 185                         | 80.0                 |
| 1990 | USA     | 241                   | 190                         | 78.8                 |
| 1995 | USA     | 249                   | 195                         | 78.3                 |
| 2000 | USA     | 257                   | 200                         | 77.8                 |
| 2005 | USA     | 265                   | 205                         | 77.3                 |
| 2010 | USA     | 273                   | 210                         | 77.0                 |
| 2015 | USA     | 281                   | 215                         | 76.5                 |
| 2020 | USA     | 289                   | 220                         | 76.1                 |
| 2025 | USA     | 297                   | 225                         | 75.8                 |
| 2030 | USA     | 305                   | 230                         | 75.4                 |
| 2035 | USA     | 313                   | 235                         | 75.1                 |
| 2040 | USA     | 321                   | 240                         | 74.8                 |
| 2045 | USA     | 329                   | 245                         | 74.5                 |
| 2050 | USA     | 337                   | 250                         | 74.2                 |
| 2060 | USA     | 345                   | 255                         | 73.9                 |
| 2070 | USA     | 353                   | 260                         | 73.6                 |
| 2080 | USA     | 361                   | 265                         | 73.4                 |
| 2090 | USA     | 369                   | 270                         | 73.2                 |
| 2100 | USA     | 377                   | 275                         | 73.0                 |

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| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 | 55 | 56 | 57 | 58 | 59 | 60 | 61 | 62 | 63 | 64 | 65 | 66 | 67 | 68 | 69 | 70 | 71 | 72 | 73 | 74 | 75 | 76 | 77 | 78 | 79 | 80 | 81 | 82 | 83 | 84 | 85 | 86 | 87 | 88 | 89 | 90 | 91 | 92 | 93 | 94 | 95 | 96 | 97 | 98 | 99 | 100 | 101 | 102 | 103 | 104 | 105 | 106 | 107 | 108 | 109 | 110 | 111 | 112 | 113 | 114 | 115 | 116 | 117 | 118 | 119 | 120 | 121 | 122 | 123 | 124 | 125 | 126 | 127 | 128 | 129 | 130 | 131 | 132 | 133 | 134 | 135 | 136 | 137 | 138 | 139 | 140 | 141 | 142 | 143 | 144 | 145 | 146 | 147 | 148 | 149 | 150 | 151 | 152 | 153 | 154 | 155 | 156 | 157 | 158 | 159 | 160 | 161 | 162 | 163 | 164 | 165 | 166 | 167 | 168 | 169 | 170 | 171 | 172 | 173 | 174 | 175 | 176 | 177 | 178 | 179 | 180 | 181 | 182 | 183 | 184 | 185 | 186 | 187 | 188 | 189 | 190 | 191 | 192 | 193 | 194 | 195 | 196 | 197 | 198 | 199 | 200 | 201 | 202 | 203 | 204 | 205 | 206 | 207 | 208 | 209 | 210 | 211 | 212 | 213 | 214 | 215 | 216 | 217 | 218 | 219 | 220 | 221 | 222 | 223 | 224 | 225 | 226 | 227 | 228 | 229 | 230 | 231 | 232 | 233 | 234 | 235 | 236 | 237 | 238 | 239 | 240 | 241 | 242 | 243 | 244 | 245 | 246 | 247 | 248 | 249 | 250 | 251 | 252 | 253 | 254 | 255 | 256 | 257 | 258 | 259 | 260 | 261 | 262 | 263 | 264 | 265 | 266 | 267 | 268 | 269 | 270 | 271 | 272 | 273 | 274 | 275 | 276 | 277 | 278 | 279 | 280 | 281 | 282 | 283 | 284 | 285 | 286 | 287 | 288 | 289 | 290 | 291 | 292 | 293 | 294 | 295 | 296 | 297 | 298 | 299 | 300 | 301 | 302 | 303 | 304 | 305 | 306 | 307 | 308 | 309 | 310 | 311 | 312 | 313 | 314 | 315 | 316 | 317 | 318 | 319 | 320 | 321 | 322 | 323 | 324 | 325 | 326 | 327 | 328 | 329 | 330 | 331 | 332 | 333 | 334 | 335 | 336 | 337 | 338 | 339 | 340 | 341 | 342 | 343 | 344 | 345 | 346 | 347 | 348 | 349 | 350 | 351 | 352 | 353 | 354 | 355 | 356 | 357 | 358 | 359 | 360 | 361 | 362 | 363 | 364 | 365 | 366 | 367 | 368 | 369 | 370 | 371 | 372 | 373 | 374 | 375 | 376 | 377 | 378 | 379 | 380 | 381 | 382 | 383 | 384 | 385 | 386 | 387 | 388 | 389 | 390 | 391 | 392 | 393 | 394 | 395 | 396 | 397 | 398 | 399 | 400 | 401 | 402 | 403 | 404 | 405 | 406 | 407 | 408 | 409 | 410 | 411 | 412 | 413 | 414 | 415 | 416 | 417 | 418 | 419 | 420 | 421 | 422 | 423 | 424 | 425 | 426 | 427 | 428 | 429 | 430 | 431 | 432 | 433 | 434 | 435 | 436 | 437 | 438 | 439 | 440 | 441 | 442 | 443 | 444 | 445 | 446 | 447 | 448 | 449 | 450 | 451 | 452 | 453 | 454 | 455 | 456 | 457 | 458 | 459 | 460 | 461 | 462 | 463 | 464 | 465 | 466 |
|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|

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**(c) [REDACTED]**

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### h. [REDACTED] [REDACTED] [REDACTED] [REDACTED]



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[REDACTED]

[REDACTED]

3 Q Okay. So sometime in that time period?

4 A Correct.

5 Q [REDACTED]

6 [REDACTED] -- you understood that there were risks  
7 with it, correct?

8 MR. DEGREEFF: Object to form.

9 A I assumed there was. There are with  
10 everything.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

23 Q Okay. Did you know anyone that had ever been  
24 treated by him before?

25 A No.

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[illegible]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

7 Q Okay. In Exhibits 1 and 2 that you signed,

8 you say that part of your claim is that your filter has

9 tilted. Do you remember seeing those in Exhibits 1 and

10 2?

11 A I do remember seeing that.

12 Q Okay. Why is that included in Exhibit 1 and

13 Exhibit 2, the information about tilt?

14 MR. DEGREEFF: Just to the extent that that

15 would require you to discuss conversations you had

16 with your attorneys, then I instruct you not to

17 answer.

18 BY MS. HELM:

19 Q Can you answer that question without revealing

20 conversations you had with your attorney?

21 A No.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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1 MS. HELM: Okay.

2 BY MS. HELM:

[illegible]



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[illegible]

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1 A No.

2 Q So you saw the ad -- you saw the popup and you  
3 saw the ad, and you said you became concerned about your  
4 filter; is that right?

5 A Correct.

6 Q Okay. And so you called a lawyer, correct?

7 A Correct.

[REDACTED]

24 Q And after you saw the ads and the popup on the  
25 Internet about the alleged problems with the filters,

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1 have now is caused by that. Not knowing, you know,  
2 whether, you know, I might have to have a surgery, could  
3 be life-threatening. I worry about, you know, pieces of  
4 it tearing up. I don't know, I just -- I just worry  
5 daily about -- where before I didn't have this worry. I  
6 worry daily about -- to some extent every day about it.  
7 If I have pains that are different than what normal  
8 pains I have, then I wonder if it's caused by the  
9 filter.

10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 Q Okay. So once you saw the ads and the  
15 pop-ups, and did the research on the Internet sometime  
16 in mid to late 2015, until late 2016, [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 [REDACTED]  
28 [REDACTED]  
29 [REDACTED]  
30 [REDACTED]

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[REDACTED]

8 Q Okay. And you found out it was harming people  
9 bad before you hired Mr. Degreeff, right?

10 A Yes.

11 Q Okay. So we know that was in October of 2015,  
12 because you told us that in Exhibit 2, correct?

13 A I believe so.

14 Q Okay. So from at least October of 2015, until  
15 the very end of 2016, in October of 2015, you had  
16 through the Internet and television ads information that  
17 told you -- that caused you to be concerned about your  
18 filter, right?

19 MR. DEGREEFF: Object to form.

20 A Right.

[REDACTED]

25 Q Okay. So you just spent that -- you just

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1 asked about bodily injuries as a result of the  
2 implantation of the filter, and do you see your answer  
3 there?

4 A Yes.

5 Q It's basically the same as your answer on  
6 Exhibit 1, isn't it?

7 A Correct.

8 Q Okay. And then, in paragraph 2, it says "When  
9 was the first time you experienced symptoms of any  
10 bodily injuries you claim in your lawsuit to have  
11 resulted from that Bard inferior vena cava filter?" Do  
12 you see that question?

13 A Yes.

[REDACTED]

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6 MR. DEGREEFF: Object to form.

7 A I don't know, it just seems like symptoms  
8 isn't the correct word to use for that, I don't know.

9 Q Well, okay. Ms. Mulkey, when you helped  
10 answer and swore that the answer to question 13B on page  
11 14 of Exhibit 2 was correct, did you understand the  
12 question?

13 A I did. I did, but --

14 Q Okay. And the question is when was the first  
15 time, correct? Do you see that? That's the very first  
16 five words.

17 A It is.

20 MR. DEGREEFF: Object to form.

21 A Yes. But I went on to say that I didn't  
22 realize at that time it was an injury. I didn't.

23 Q Okay. But that's not the question. The  
24 question is when was the first time you experienced  
25 symptoms?

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1           A     That's what I'm saying. Symptom is -- is I  
2     don't know. I didn't pay no attention, I guess when it  
3     said symptoms maybe. Symptoms, now, just don't seem  
4     like the right, appropriate word to be there.

5           Q     Well --

6           A     But it is.

7           Q     -- with all due respect, ma'am, the question  
8     -- we were entitled to ask the question, and your  
9     responsibility was to answer the question under oath.

10          A     Right.

11          Q     So you -- this is your answer under oath --

12          A     That is my answer.

13          Q     Okay. Okay. On 13C, when it says "When did  
14     you first attribute the injuries to your filter," the  
15     symptoms of the -- we've talked about the injuries in A,  
16     the pain, suffering and mental anguish and loss of  
17     enjoyment of life. We talked about when you started  
18     experiencing those symptoms in B, and then in C, the  
19     question is "When did you attribute those to your  
20     filter," and you said "When I saw an ad on TV in 2015 --  
21     in October 2015," right?

22          A     Correct.

23     [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

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[REDACTED]

16 Q Okay.

17 A It just seemed better to put they in there.

18 Q Okay. But that's not the question. You agree  
19 with me, right? That's not the question?

20 A Yeah, that's kind of right up there with the  
21 symptom one, yeah.

22 Q Okay. And then let's look at 13E on page 15  
23 of Exhibit 2. It says "To the best of your knowledge  
24 and recollection, has any healthcare provider ever told  
25 you orally or in writing that any symptoms related to



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1     bodily injury are related to the Bard Inferior Vena Cava  
2     filter?" [REDACTED] [REDACTED] [REDACTED]

3     [REDACTED] [REDACTED] [REDACTED]

4     [REDACTED]

5             Q     Okay. Okay. Then it gets to F and it says  
6     "Are you currently experiencing symptoms related to your  
7     claimed bodily injuries," and you said "Yes," correct?

8             A     Correct.

9             Q     And then you've said "I have mental anguish  
10    that the filter remains in my body, and that it can  
11    fracture or migrate causing me bodily injury in the  
12    future." Is that -- are those your words?

13            A     I don't think I used the word migrate. I put  
14    move or shift.

15            Q     Okay. So somebody changed your words?

16            A     Sounded more professional.

17            Q     Okay. And then you said "I worry about having  
18    a second removal of the IVC filter and whether it will  
19    be able to remove without causing me bodily injury," and  
20    we've talked about that, right?

21            A     Right. Correct.

22            Q     [REDACTED] [REDACTED] [REDACTED]

23    [REDACTED]

24    [REDACTED]

25    [REDACTED]

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[REDACTED] [REDACTED]  
 [REDACTED]  
 [REDACTED] [REDACTED]  
 [REDACTED]

1. [REDACTED]  
 2. [REDACTED]  
 3. [REDACTED]

1. [REDACTED] [REDACTED]

2. [REDACTED] [REDACTED]

1. [REDACTED] [REDACTED] [REDACTED] [REDACTED]

2. [REDACTED] [REDACTED] [REDACTED] [REDACTED]

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

1. **Introduction**

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4. **Results**

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[illegible]

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\_\_\_\_\_  
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\_\_\_\_\_

\_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_

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1 A No.

2 Q At that point, did you believe that there was  
3 anything defective about your filter?

4 MS. HELM: Object to the form.

5 A No.

6 Q At that point, did you believe that you had  
7 been wronged by the defendant manufacturer, Bard, or any  
8 other manufacturer of a filter?

9 MS. HELM: Object to the form.

10 A No.

11 [REDACTED]

[REDACTED]

[REDACTED]

14 Q When did you first become aware that you were  
15 injured by the filter?

16 A [REDACTED]

17 Q Okay. And that was the date that defense  
18 counsel continually asked you about, right?

19 MS. HELM: Objection to the form.

20 A Yes.

21 Q And when did you first realize that there may  
22 be something defective about the filter?

23 A Late 2015.

24 Q And when did you first realize that you may  
25 have been wronged by the defendants, in this case, Bard,

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[REDACTED]

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17 Q You were asked some questions about Exhibit 1  
18 and 2, which is the plaintiff's profile form and the  
19 plaintiff's fact sheet; do you remember that?

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1 allowed to claim and what you're not allowed to claim?

2 A No.

[REDACTED]

**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**EXHIBIT M-E - REDACTED**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA

MDL No. 2641

*In Re Bard IVC Filter Products Liability Litigation*

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**PLAINTIFF FACT SHEET**

Each plaintiff who allegedly suffered injury as a result of a Bard Inferior Vena Cava Filter must complete the following Plaintiff Fact Sheet ("Plaintiff Fact Sheet"). In completing this Fact Sheet, you are **under oath and must answer every question.** You must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details as requested, please provide as much information as you can and then state that your answer is incomplete and explain why, as appropriate. If you select an "I Don't Know" answer, please state all that you do know about that subject. If any information you need to complete any part of the Fact Sheet is in the possession of your attorney, please consult with your attorney so that you can fully and accurately respond to the questions set out below. If you are completing the Fact Sheet for someone who cannot complete the Fact Sheet for himself/herself, please answer as completely as you can.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and responses to requests for production pursuant to Fed. R. Civ. P. 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. Therefore, you must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production of documents contained in this Fact Sheet are non-objectionable and shall be answered without objection. This Fact Sheet shall not preclude Bard Defendants from seeking additional documents and information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

In filling out this form, "healthcare provider" shall mean any medical provider, doctor, physician, surgeon, pharmacist, hospital, clinic, medical center, physician's office, infirmary, medical/diagnostic laboratory, or any other facility that provides medical care or advice, along with any pharmacy, x-ray department, radiology department, laboratory, physical therapist/physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in your diagnosis, care and/or treatment.

In filling out this form, the terms "You" or "Your" refer to the person who received a Bard Inferior Vena Cava Filter manufactured and/or distributed by C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. ("Bard Defendants") and who is identified in Question 1(a) below.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary. Please identify any documents that you are



producing responsive to a question with Bates Stamp identifiers. Information provided by Plaintiff will only be used for the purposes related to this litigation and may be disclosed only as permitted under the protective order in this litigation.

### I. BACKGROUND INFORMATION

1. Please state:

- (a) Full name of the person who received the Bard inferior vena cava filter, including maiden name: [REDACTED] - Maiden Name: [REDACTED]
- (b) List all names by which you have ever been known, if different from that listed in 1(a): [REDACTED]
- (c) Full name of the person completing this form, if different from the person listed in 1(a) above, and the relationship of the person completing this form to the person listed in 1(a) above: \_\_\_\_\_
- (d) The name and address of your primary attorney:  
David C. DeGreeff  
Wagstaff & Cartmell LLP  
4740 Grand Ave., Ste. 300  
Kansas City, MO 64112
- (e) When did you first retain an attorney to represent you in your lawsuit against Bard?  
10/14/2015

2. Your Social Security Number: [REDACTED]

3. Your Date of Birth: [REDACTED]

4. Your current residential address:

[REDACTED]

5. If you have lived at this address for less than 10 years, provide each of your prior residential addresses from 2000 to the present:

| Prior Residential Address | Dates You Lived At This Address |
|---------------------------|---------------------------------|
|---------------------------|---------------------------------|

|   |  |
|---|--|
| <div style="background-color: black; width: 100%; height: 100%;"></div> |  |
|   |  |
|   |  |
|   |  |

6. Have you ever been married? Yes ☐ No ☐
- If yes, provide the names and addresses of each spouse and the inclusive dates of your marriage to each person:

|   |
|---|
| <div style="background-color: black; width: 100%; height: 100%;"></div> |
|---|

7. Do you have children? Yes ☐ No ☐
- If Yes, please provide the following information with respect to each child:

| Full Name of Child  | Date of Birth | Home Address | Whether Biological/Adopted |
|---|---------------|--------------|----------------------------|
| <div style="background-color: black; width: 100%; height: 100%;"></div> |               |              |                            |
|   |               |              |                            |
|   |               |              |                            |
|   |               |              |                            |

8. Identify the name and age of any person who currently resides with you and their relationship to you:

|   |
|---|
| <div style="background-color: black; width: 100%; height: 100%;"></div> |
|---|

9. Identify the name and age of any person who has resided with you at any point over the past ten (10) years:

|   |
|---|
| <div style="background-color: black; width: 100%; height: 100%;"></div> |
|---|

10. Identify all secondary and post-secondary schools you attended, starting with high school, and please provide the following information with respect to each:

| Name of School | Address | Dates of Attendance | Degree Awarded | Major or Primary Field of Study |
|----------------|---------|---------------------|----------------|---------------------------------|
|                |         |                     |                |                                 |
|                |         |                     |                |                                 |
|                |         |                     |                |                                 |
|                |         |                     |                |                                 |

11. Please provide the following information for your employment history over the past 10 years up until the present:

| Employer Name | Address | Job Title/Description of Duties | Dates of Employment | Salary/Rate of Pay |
|---------------|---------|---------------------------------|---------------------|--------------------|
|               |         |                                 |                     |                    |
|               |         |                                 |                     |                    |
|               |         |                                 |                     |                    |
|               |         |                                 |                     |                    |
|               |         |                                 |                     |                    |

12. Have you ever served in any branch of the military? Yes \_\_\_\_\_ No X

If Yes, please provide the following information:

- (a) Branch and dates of service, rank upon discharge, and type of discharge received:

\_\_\_\_\_

- (b) Were you discharged from the military at any time for any reason relating to your medical, physical, or psychiatric condition? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, state what that condition was: \_\_\_\_\_

13. Within the last ten years, have you been convicted of, or plead guilty to, a felony and/or crime of fraud or dishonesty? Yes \_\_\_\_\_ No X

If Yes, please set forth where and when and identify the felony and/or crime:

14. Before contacting any attorney regarding this lawsuit or claim, had you ever seen any television or print advertisements regarding possible claims against inferior Vena Cava Filter manufacturers? Yes X No \_\_\_\_\_

If Yes, set forth the approximate date and nature of any such advertisement, whether the advertisement included the name of a law firm, whether the advertisement specifically mentioned C. R. Bard, Inc., Bard Peripheral Vascular, Inc., or "Bard", and other details that you recall. Yes, latter part of 2015, but do not remember the name of the law firm or if Bard was mentioned. I do not remember if it mentioned Bard.

## II. CLAIM INFORMATION

1. Have you ever received a Bard Inferior Vena Cava Filter? Yes ☐ No ☐  
If Yes, please check the box(es) for each type of Bard Inferior Vena Cava Filter you have received:

☐ Recovery®

☐ G2®

☐ G2®X

☐ G2®Express

☐ Eclipse®

☐ Meridian®

☐ Denali®

☐ Simon Nitinol

☐ Other (please identify): \_\_\_\_\_

2. For each Bard Inferior Vena Cava Filter identified above, please provide the following information:

(a) The date each Bard Inferior Vena Cava Filter was implanted in you:

\_\_\_\_\_

(b) The product code and lot number of each Bard Inferior Vena Cava Filter implanted in you:

\_\_\_\_\_

(c) Current location of the Bard Inferior Vena Cava Filter, including any portion thereof, if known:

\_\_\_\_\_

\_\_\_\_\_

3. Describe your understanding of the medical condition for which you received the Bard Inferior Vena Cava Filter(s):

\_\_\_\_\_

4. Give the name and address of the doctor who implanted the Bard Inferior Vena Cava Filter(s): \_\_\_\_\_

5. Give the name and address of the hospital or other healthcare facility where the Bard Inferior Vena Cava Filter was implanted: \_\_\_\_\_

\_\_\_\_\_

6. Have you ever been implanted with any other vena cava filters or related product(s) besides the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar condition(s) identified in your response to question 3 above? Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes:

(a) Please identify any such device(s) or product(s). \_\_\_\_\_

\_\_\_\_\_

(b) When was this device or product implanted in you? \_\_\_\_\_

- (c) Did the implantation take place before, at the same time, or after the procedure during which you were implanted with a Bard Inferior Vena Cava Filter? \_\_\_\_\_
- (d) Who was the physician who implanted this other device or product? \_\_\_\_\_
- (e) At what hospital or facility was this other device or product implanted in you? \_\_\_\_\_
- (f) Why was this other device or product implanted in you? \_\_\_\_\_
7. Other than the Bard Inferior Vena Cava Filter device that is the subject of your lawsuit or identified in response to question 6 above, are you aware of any other Vena Cava Filter(s) implanted inside your body at any time? Yes ☐ No ☐
- If yes, please provide the following information:
- (a) Product name: \_\_\_\_\_
- (b) Date of procedure placing it and name and address of doctor who placed it: \_\_\_\_\_
- (c) Condition sought to be treated through placement of the device: \_\_\_\_\_
- (d) Any complications you encountered with the medical product or procedure: \_\_\_\_\_
- (e) Does that product remain implanted inside of you today? Yes \_\_\_\_\_ No \_\_\_\_\_
8. Prior to implantation with a Bard Inferior Vena Cava Filter, did you receive any written and/or verbal information or instructions regarding the Bard Inferior Vena Cava Filter, including any risks or complications that might be associated with the use of the same? Yes ☐ No ☐ Don't Know ☐

If Yes:

- (a) Provide the date you received the written and/or verbal information or instructions:

---

---

- (b) Identify by name and address the person(s) who provided the information and instructions:

---

---

- (c) What information or instructions did you receive?

---

---

- (d) If you have copies of the written information or instructions you received, please attach copies to your response.

---

---

- (e) Were you told of any potential complications from the implantation of the Bard Inferior Vena Cava Filter(s)? Yes ☐ No ☐ Don't Know ☐

- (f) If yes to (e), by whom?

---

---

- (g) If yes to (e), what potential complications were described to you?

---

---

9. Do you believe that the Bard Inferior Vena Cava Filter(s) remains implanted in you?

Yes ☐ No ☐ Don't Know ☐

If Yes:

- (a) Has any doctor recommended removal of the Bard Inferior Vena Cava Filter(s)?

Yes ☐ No ☐

If Yes:

- (i) Identify by name and address every doctor who recommended removal of the Bard Inferior Vena Cava Filter(s): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- (ii) For each doctor identified in response to question 8(a)(i) above, state your understanding of why the doctor recommended removal. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- (iii) For each doctor identified in response to question 8(a)(i) above, state when the doctor recommended removal. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

10. Has the Bard Inferior Vena Cava Filter(s) implanted in you been removed, in whole or in part?

Yes \_\_\_\_\_ No \_\_\_\_\_ Don't Know \_\_\_\_\_

If Yes:

- (a) Where, when, and by whom was the Bard Inferior Vena Cava Filter(s), or any portion of it, removed? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- (b) What portion of the Bard Inferior Vena Cava Filter(s) was removed on the date indicated in response to question 9(a) above? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- (c) Please check all that apply regarding the removal procedure(s):
- ☐ Removed percutaneously
  - ☐ Removed via an open abdominal procedure
  - ☐ Removed via an open chest procedure
  - ☐ Other, Describe: \_\_\_\_\_
  - ☐ Unknown



(d) Does any portion of the Bard Inferior Vena Cava Filter(s) remain implanted in you? Yes \_\_\_\_\_ No \_\_\_\_\_ Don't Know \_\_\_\_\_  
If Yes, explain what portion of the Bard Inferior Vena Cava Filter(s) you believe is still implanted in you: \_\_\_\_\_

(e) Explain why you consented to have the Bard Inferior Vena Cava Filter(s), or any portion thereof, removed?  
\_\_\_\_\_

(f) Does any medical provider, physician, entity, or anyone else acting on your behalf have possession of any portion of the Bard Inferior Vena Cava Filter that was previously implanted in you and subsequently removed?  
Yes \_\_\_\_\_ No \_\_\_\_\_ Don't Know \_\_\_\_\_  
If Yes, please state the name and address of the person or entity having possession of same. \_\_\_\_\_  
\_\_\_\_\_

11. Has any doctor or healthcare provider unsuccessfully attempted to remove the Bard Inferior Vena Cava Filter(s) implanted in you?

Yes [REDACTED] No [REDACTED] Don't Know [REDACTED]

If Yes:

(a) How many attempts have been made to remove the Bard Inferior Vena Cava Filter(s) implanted in you? [REDACTED]

(b) Provide the name and address of the doctor who removed (or attempted to remove) the filter strut(s) and the hospital or medical facility at which it was removed (or attempted to be removed).

Filter Removal/Attempted Removal #1

Doctor: [REDACTED]

Hospital/Medical Facility: [REDACTED]

Date: [REDACTED]

Filter Removal/Attempted Removal #2

Doctor: \_\_\_\_\_

Hospital/Medical Facility: \_\_\_\_\_

Date: \_\_\_\_\_


Filter Removal/Attempted Removal #3

Doctor: \_\_\_\_\_

Hospital/Medical Facility: \_\_\_\_\_

Date: \_\_\_\_\_

- (c) Please check all that apply regarding attempted removal procedure #1:

 Attempted but unsuccessful percutaneous removal procedure

Attempted but unsuccessful open abdominal procedure

Attempted but unsuccessful open chest procedure

Other, Describe: \_\_\_\_\_

\_\_\_\_\_

Unknown

- (d) Please check all that apply regarding attempted removal procedure #2:

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: \_\_\_\_\_

\_\_\_\_\_

☐ Unknown

- (e) Please check all that apply regarding attempted removal procedure #3:

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: \_\_\_\_\_

\_\_\_\_\_

☐ Unknown

12. Do you claim that your Bard Inferior Vena Cava Filter(s) fractured?

Yes

No

If Yes:

(i) Please state the number of fractured struts retained in your body?

(ii) Please identify the location(s) within your body of each retained filter strut.

(iii) Please provide the date or approximate date when you were first informed of each fractured strut.

(iv) Has any health care provider recommended to you that a retained filter strut(s) should be removed?

Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.

(v) Has any health care provider recommended to you that a retained filter strut should not be removed?

Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.

- (vi) Have any fractured struts been removed, or attempted to have been removed, from your body?

Yes \_\_\_\_\_ No \_\_\_\_\_

If Yes:

- (1) If any fractured filter strut has been removed (or a doctor has attempted to remove any strut), please check all that apply regarding the removal/attempted removal procedure(s):
- ☐ Removed percutaneously
  - ☐ Removed via an open abdominal procedure
  - ☐ Removed via an open chest procedure
  - ☐ Attempted but unsuccessful percutaneous removal procedure
  - ☐ Attempted but unsuccessful open abdominal procedure
  - ☐ Attempted but unsuccessful open chest procedure
  - ☐ Other, Describe: \_\_\_\_\_
  - ☐ Unknown
- (2) Provide the name and address of the doctor who removed (or attempted to remove) the filter strut(s) and the hospital or medical facility at which it was removed (or attempted to be removed).
- Filter Strut Removal/Attempted Removal #1
- Doctor: \_\_\_\_\_
- Hospital/Medical Facility: \_\_\_\_\_
- Date: \_\_\_\_\_
- Filter Strut Removal/Attempted Removal #2
- Doctor: \_\_\_\_\_
- Hospital/Medical Facility: \_\_\_\_\_
- Date: \_\_\_\_\_

13. Do you claim that you suffered bodily injuries as a result of the implantation of the Bard Inferior Vena Cava Filter(s)? Yes ☐ No ☐

If Yes:

- (a) Describe the bodily injuries, including any emotional or psychological injuries that you claim resulted from the implantation, attempted removal and/or removal of the Bard Inferior Vena Cava Filter(s)?

[REDACTED]

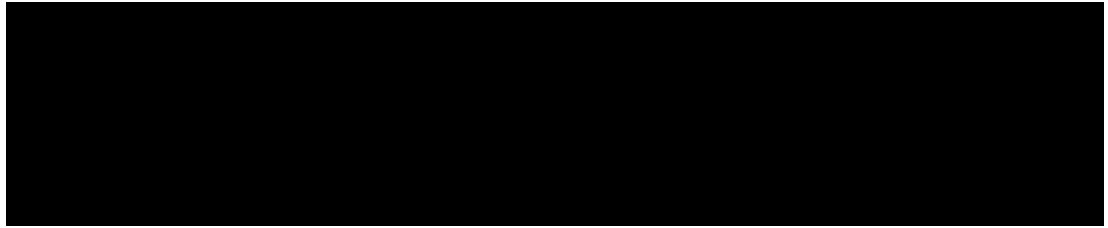
- (b) When was the first time you experienced symptoms of any of the bodily injuries you claim in your lawsuit to have resulted from the Bard Inferior Vena Cava Filter(s)?

[REDACTED]

- (c) When did you first attribute these bodily injuries to the Bard Inferior Vena Cava Filter(s)?

[REDACTED]

- (d) To the best of your knowledge and recollection, please state the approximate date when you first saw a health care provider for any of the bodily injuries, or symptoms related thereto, you claim to have experienced related to the Bard Inferior Vena Cava Filter(s)?



- (e) To the best of your knowledge and recollection, has any health care provider ever told you orally or in writing that any symptoms related to bodily injury are related to the Bard Inferior Vena Cava Filter(s)?

Yes ☐ No ☐

If Yes, please state the name and address of any such health care provider, as well as providing the approximate date the statement was made, and provide the details of the communication: \_\_\_\_\_

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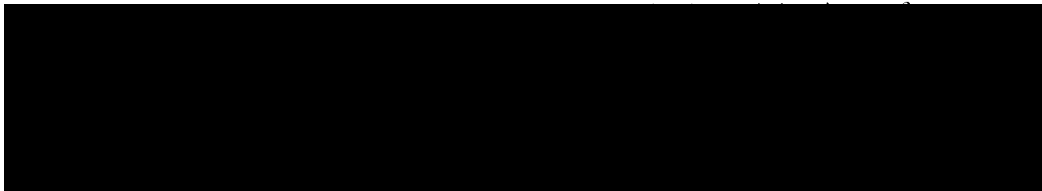


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- (f) Are you currently experiencing symptoms related to your claimed bodily injuries?

Yes ☐ No ☐

If Yes, please describe your symptoms in detail:



- (g) Are you currently seeing, or have you ever seen, a doctor or healthcare provider for any of the bodily injuries or symptoms listed above?

Yes ☐ No ☐

If Yes, please list all doctors you have seen for treatment of any of the bodily injuries you have listed above.

| Provider Name and Address | Condition Treated | Approximate Dates of Treatment |
|---------------------------|-------------------|--------------------------------|
|                           |                   |                                |
|                           |                   |                                |

|  |  |  |
|--|--|--|
|  |  |  |
|--|--|--|

h) Were you hospitalized at any time for the bodily injuries you listed above?

Yes ☐ No ☐

If Yes, please provide the following:

| Hospital Name and Address | Condition Treated | Approximate Dates of Treatment |
|---------------------------|-------------------|--------------------------------|
|                           |                   |                                |
|                           |                   |                                |
|                           |                   |                                |

14. Are you making a claim for lost wages or lost earning capacity?

Yes \_\_\_\_\_ No X

(a) If yes, state the annual gross income derived from your employment for each year, beginning five (5) years prior to the implantation of the Bard Inferior Vena Cava Filter(s) until the present: \_\_\_\_\_

\_\_\_\_\_

(b) If yes, for what period of time are you claiming lost wages? \_\_\_\_\_

\_\_\_\_\_

(c) If you are claiming lost earning capacity, do you claim that you have a claim for future lost wages?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, for what period of time do you claim you have lost future wages?

\_\_\_\_\_

\_\_\_\_\_

15. Are you making a claim for lost out-of-pocket expenses? Yes X No \_\_\_\_\_

If yes, please identify and itemize all out-of-pocket expenses you have incurred.

Past medical bills and expenses, future medical care and expenses including without limitation removal surgery (or surgeries) and medical monitoring, and any other damages revealed during discovery.

\_\_\_\_\_

\_\_\_\_\_

16. Has anyone filed a loss of consortium claim in connection with your lawsuit regarding the Bard Inferior Vena Cava Filter(s)?

Yes \_\_\_\_\_ No X

If yes, identify by name and address the person who filed the loss of consortium claim ("Consortium Plaintiff") and state the relationship of that person to you and state the specific nature of the Consortium Plaintiff's claim. \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

17. Please indicate whether the Consortium Plaintiff alleges any of the damages set forth below: Not Applicable

| Claims                                    | Yes/No |
|---|--------|
| Loss of services of spouse                |        |
| Impaired sexual relations                 |        |
| Lost wages/lost earning capacity          |        |
| Lost out-of-pocket expenses               |        |
| Physical injuries                         |        |
| Psychological injuries/emotional injuries |        |
| Other                                     |        |

18. Please list the name and address of any healthcare providers the Consortium Plaintiff has sought treatment for any physical, emotional, or psychological injuries or symptoms alleged to be related to his/her claim. Not applicable
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_



19. Have you or anyone acting on your behalf had any communication, oral or written, with any of the Bard Defendants and/or their representatives?

Yes \_\_\_\_\_ No X Don't Know \_\_\_\_\_

If yes, set forth: (a) the date of any communication, (b) the method of communication, (c) the name of the person with whom you communicated, and (d) the substance of the communications. \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

### III. MEDICAL BACKGROUND

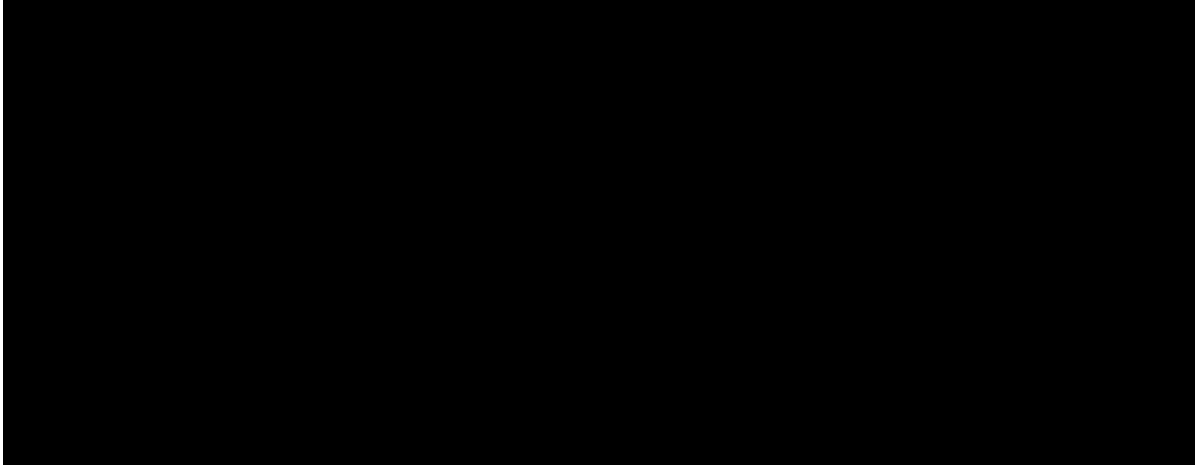
1. Provide your current: Age        Height        Weight
2. Provide your: Age        Weight        (approximate, if unknown) at the time the Bard Inferior Vena Cava Filter was implanted in you.
3. In chronological order, list any and all surgeries, procedures and/or hospitalizations you had in the ten (10) year period BEFORE implantation of the Bard Inferior Vena Cava Filter(s). Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

| Approximate Date | Description of Surgery or Hospitalization | Doctor or Healthcare Provider Involved (including address) |
|------------------|---|--|
|                  |   |  |
|                  |   |  |
|                  |   |  |
|                  |   |  |

*[Attach additional sheets as necessary to provide the same information for any and all surgeries and hospitalizations leading up to the implantation of the Bard Inferior Vena Cava Filter.]*

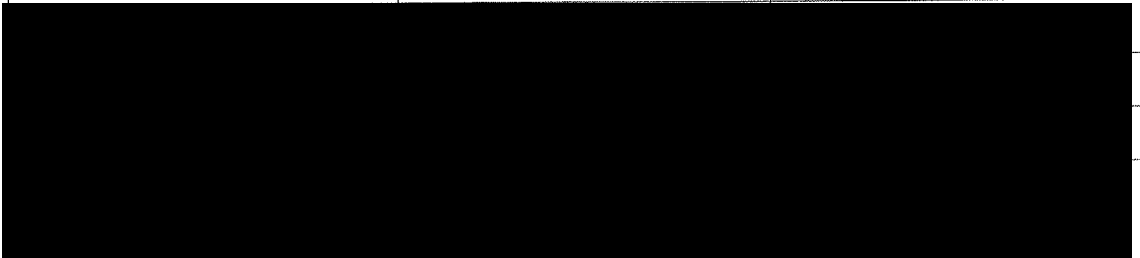
4. In chronological order, list any and all surgeries, procedures and/or hospitalizations you had AFTER implantation of the Bard Inferior Vena Cava Filter(s). Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

| Approximate Date | Description of Surgery or Hospitalization | Doctor or Healthcare Provider Involved (including address) |
|------------------|---|--|
|------------------|---|--|



*[Attach additional sheets as necessary to provide the same information for any and all surgeries and hospitalizations after the implantation of the Bard Inferior Vena Cava Filter.]*

5. To the extent not already provided in the charts above, provide the name, address, and telephone number of every doctor, hospital or other health care provider from which you have received medical advice and/or treatment from ten (10) years before the date the filter was implanted to the present:

| Name and Specialty   | Address | Approximate Date/Years of Visits |
|--|---------|----------------------------------|
|  |         |                                  |
|  |         |                                  |
|  |         |                                  |
|  |         |                                  |

6. *Before the implantation* of the Bard Inferior Vena Cava Filter(s), did you regularly exercise or participate in activities that required lifting or strenuous physical activity? (Please include all physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)

Yes \_\_\_\_\_ No x

If yes, please describe each activity in detail. \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

7. *Since the implantation* of the Bard Inferior Vena Cava Filter(s), have you regularly exercised or participated in activities that required lifting or strenuous physical activity? (Please describe all range of physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)

Yes X No \_\_\_\_\_

If yes, please describe each activity in detail. \_\_\_\_\_

Walking, household chores

\_\_\_\_\_

\_\_\_\_\_

8. During the past ten (10) years, what have been your primary hobbies or recreational activities? \_\_\_\_\_

Cake Making/Decorating, reading, TV, crafts, coloring, playing with my grandchildren, outdoor concerts and festivals

\_\_\_\_\_

\_\_\_\_\_

- (a) Do you claim that you are unable to participate in any of the hobbies or recreational activities listed in response to question 8 above as a result of you having been implanted with a Bard Inferior Vena Cava Filter(s)?

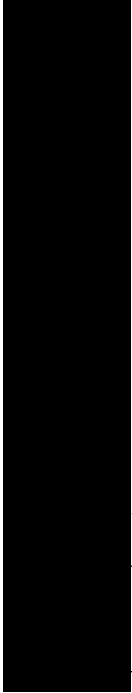
Yes \_\_\_\_\_ No X

- (b) If yes, what hobbies or recreational activities do you claim that you are unable to participate in as a result of having been implanted with a Bard Inferior Vena Cava Filter(s)? \_\_\_\_\_

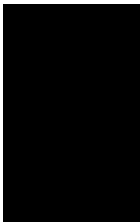
- (c) For what period of time do you claim that you were or have been unable to participate in any hobbies or recreational activities as a result of having been implanted with a Bard Inferior Vena Cava Filter(s)?

N/A

9. To the best of your knowledge, have you ever been told by a doctor or another health care provider that you have suffered, may have suffered, or presently do suffer from any of the following:

 Lupus  
Crohn's Disease  
Factor V Leiden  
Protein Deficiency  
Spinal Fusion or Other Back Procedures  
Anti-thrombin Deficiency  
Prothrombin Mutation  
Deep Vein Thrombosis  
Pulmonary Embolism  
Auto Immune Disorder  
Varicose Veins  
Heart Procedures  
Blood Disorder

Please Describe: \_\_\_\_\_

 Bariatric Surgery  
Anticoagulation Medication (e.g., Coumadin, Warfarin, etc.)  
Ulcerative Colitis/Inflammatory Bowel Disease (IBD)  
Cancer

Please Describe: \_\_\_\_\_

\* \* \* \* \*

THE FOLLOWING QUESTIONS ARE CONFIDENTIAL AND SUBJECT TO THE PROTECTIVE ORDER APPLICABLE TO THIS CASE.

- (A) Have you been diagnosed with and/or treated for any drug, alcohol, chemical and/or other addiction or dependency during the five (5) years prior to the filing of this lawsuit through the present? Yes ☐ No ☐  
If yes, specify type and time period of dependency, type of treatment received, name of treatment provider, and current status of condition:

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- (B) Have you experienced, been diagnosed with or received psychiatric or psychological treatment of any type, including therapy, for any mental health conditions including depression, anxiety, or other emotional or psychiatric disorders during the five (5) years prior to the filing of this lawsuit through the present? Yes ☐ No ☐  
If yes, specify condition, date of onset, medication/treatment, treating physician and current status of condition:

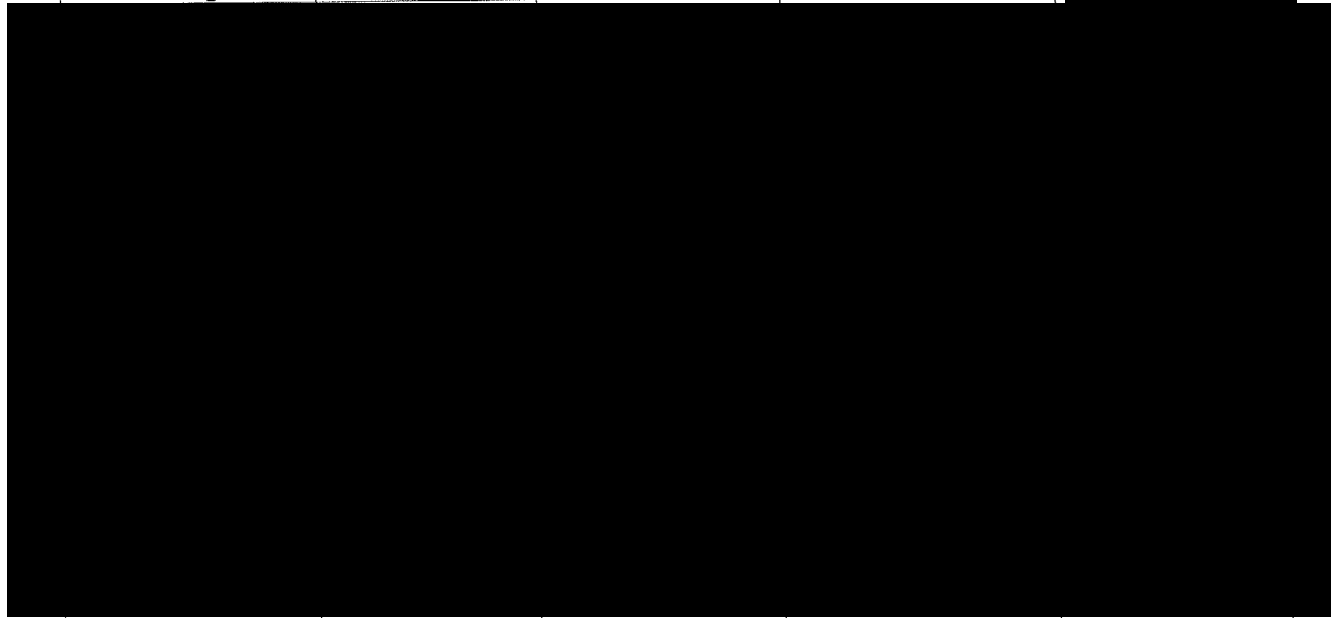
\* \* \* \* \*

10. Do you now or have you ever smoked tobacco products? Yes X No         
If yes:

How long have/did you smoke? 10 years, quit for a year, 3 years

11. List each prescription medication you have taken for more than three (3) months at a time during the timeframe beginning five (5) years prior to implantation of the Bard Inferior Vena Cava Filter and continuing to the present, giving the name and address of the pharmacy where you received/filled the medication, the reason you took the medication, and the approximate dates of use.

| Medication and Dosage | Prescribing Physician | Pharmacy Name and Address | Reason for Taking Medication | Approximate Date(s) of Use |
|-----------------------|-----------------------|---------------------------|------------------------------|----------------------------|
|-----------------------|-----------------------|---------------------------|------------------------------|----------------------------|



#### IV. INSURANCE INFORMATION

1. Provide the following information for any past or present medical insurance coverage from the timeframe beginning five (5) years prior to implantation of the Bard Inferior Vena Cava Filter and continuing to the present:

| Insurance Company Name and Address  | Policy Number | Name of Policy Holder/Insured (if different than yourself) | Approximate Dates of Coverage |
|-------------------------------------|---------------|--|-------------------------------|
| Medicare                            | 233903055W6   |  | 2011 to present               |
| Medicaid                            | 00700209054   |  | 2011 to present               |
| No health insurance<br>2007 to 2010 |               |  |                               |

2. To the best of your knowledge, have you ever been approved to receive or are you currently receiving Medicare/Medicaid benefits due to age, disability, condition, or any other reason or basis?

Yes X No

If yes, please specify the date on which you first became eligible: 2011

*[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]*

## V. PRIOR CLAIM INFORMATION

1. Have you filed a lawsuit or made a claim in the last ten (10) years, other than in the present suit relating to any bodily injury?

Yes                      No      X  

If yes, please specify the following:

- (a) Court in which the lawsuit/claim was filed or initiated: \_\_\_\_\_
- \_\_\_\_\_
- (b) Case/Claim Number: \_\_\_\_\_
- (c) Nature of Claim/Injury: \_\_\_\_\_

2. Have you ever applied for Workers' Compensation (WC), Social Security disability (SSI or SSD) benefits, or other State or Federal disability benefits?

Yes X No \_\_\_\_\_

If yes, please specify the following:

- (a) Date (or year) of application: 2009 or 2010
- (b) Type of benefits sought: SSD
- (c) Agency/Insurer from which you sought the benefits: SSA
- (d) Nature of the claimed injury/disability: Depression, weight, back injury
- (e) Whether the claim was accepted or denied: Accepted

## VI. FACT WITNESSES

1. Identify by name, address, and relationship to you, all persons (other than your healthcare providers) who possess information concerning your injuries and/or current medical condition:

| Name             | Address           | Relationship to You | Information You Believe Person Possesses   |
|------------------|-------------------|---------------------|--|
| Angelic Thompson | Fort Gay, WV      | Daughter            | My mental anguish of fear of future injury |
| Lorelei Thompson | West Van Lear, KY | Daughter            | My mental anguish of fear of future injury |
| Joshua Thompson  | Fort Gay, WV      | Son                 | My mental anguish of fear of future injury |

## VII. IDENTIFICATION OF DOCUMENTS AND OTHER ELECTRONICALLY STORED INFORMATION

For the period beginning three (3) years prior to the implantation of the Bard Inferior Vena Cava Filter until the present, please identify all research, including on-line research, that you conducted regarding the medical complaints or condition for which you received the Bard Inferior Vena Cava Filter (pulmonary thromboembolism, anticoagulant therapy, etc.) Identify the date, time, and source, including any websites visited. (Research conducted subsequent to and for the purpose of understanding the legal and strategic advice of your counsel is not considered responsive to this request.)

N/A

## VIII. DOCUMENT REQUESTS

1. RELEASES.

**NOTE:** Please sign and attach to this Fact Sheet the authorizations for the release of records appended hereto.



2. DOCUMENTS. State whether you have any of the following documents in your possession, custody, and/or control. If you do, please provide a true and correct copy of any such documents with this completed Fact Sheet. Please ensure that the production of documentation includes specific reference to the questions to which the document is provided in response, and please identify any documents you are producing responsive to a question with Bates Stamp identifiers.

(a) If you were appointed by a Court to represent the plaintiff in this lawsuit, produce any documents demonstrating such appointment.

(i) Not applicable     X    

(ii) The documents are attached          [OR] I have no documents         

(b) If you represent the Estate of a deceased person in this lawsuit, produce a copy of the decedent's death certificate and autopsy report (if applicable).

(i) Not applicable     X    

(ii) The documents are attached          [OR] I have no documents         

(c) Produce each and every medical record of each and every medical facility, pharmacy, or practitioner of the healing arts identified by you in response to the questions in Sections II and III above regarding your medical care and history for the time period beginning ten (10) years prior to the implantation of the Bard Inferior Vena Cava Filter and continuing to the present.

(i) Not applicable                         

**Records requested but not received. They will be provided when received.**

(ii) The documents are attached:          [OR] I have no documents     X    

(d) Produce any communication (sent or received) in your possession, which shall include materials accessible to you from any computer on which you have sent or received such communications, concerning the Bard Inferior Vena Cava Filter(s) or subject of this litigation, including, but not limited to all letters, emails, blogs, Facebook posts, Tweets, newsletters, etc. sent or received by you. (Research conducted subsequent to and to understand the legal and strategic advice of your counsel is not considered responsive to this request.)

(i) Not applicable     X    

(ii) The documents are attached          [OR] I have no documents

- (e) Produce all documents, including journal entries, lists, memoranda, notes, diaries, photographs, video, DVDs or other media, discussing or referencing the Bard Inferior Vena Cava Filter(s), the injuries and/or damages you claim resulted from the Bard Inferior Vena Cava Filter(s), and/or evidencing your physical condition from three (3) years prior to the implantation of the Bard Inferior Vena Cava Filter(s) to present. (Research conducted subsequent to and to understand the legal and strategic advice of your counsel is not considered responsive to this request.)
- (i) Not applicable       X
- (ii) The documents are attached        [OR] I have no documents
- (f) Produce any Bard Inferior Vena Cava Filter product packaging, labeling, advertising, or any other product-related items in your possession, custody or control.
- (i) Not applicable
- (ii) The documents are attached   X   [OR] I have no documents
- (g) Produce all documents concerning any communication between you, your attorney(s), your agent(s), your expert(s), or your representative(s) and the Food and Drug Administration (FDA), or between you and any employee or agent of the Bard Defendants, regarding Bard Inferior Vena Cava Filters.
- (i) Not applicable       X
- (ii) The documents are attached        [OR] I have no documents
- (h) Produce all documents that you, your attorney(s), your agent(s), your expert(s), or your representative(s) provided to the Food and Drug Administration (FDA) and/or the Department of Health and Human Services regarding Bard Inferior Vena Cava Filters.
- (i) Not applicable       X
- (ii) The documents are attached        [OR] I have no documents
- (i) Produce all documents concerning any communication between you, your attorney(s), your agent(s), your expert(s), or your representative(s) with anyone at any television station, radio station, newspaper, periodical, magazine, weblog, internet website, or any other media outlet regarding Bard Inferior Vena Cava Filters.

- (i) Not applicable   X
- (ii) The documents are attached        [OR] I have no documents
- (j) Produce all documents that you, your attorney(s), your agent(s), your expert(s), or your representative(s) provided to anyone at any television station, radio station, newspaper, periodical, magazine, weblog, internet website, or any other media outlet regarding Bard Inferior Vena Cava Filters.
- (i) Not applicable   X
- (ii) The documents are attached        [OR] I have no documents
- (k) Produce all documents in your possession, custody, or control evidencing or relating to any correspondence or communication between C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. (or any related companies or divisions) and any of your doctors, healthcare providers, and/or you relating to Bard Inferior Vena Cava Filters, except as to those communications which are protected by the attorney-client privilege or attorney work product doctrine.
- (i) Not applicable   X
- (ii) The documents are attached        [OR] I have no documents
- (l) Produce all documents in your possession, custody, or control reflecting, describing, or in any way relating to any instructions or warnings you received prior to implantation of any Inferior Vena Cava Filter(s) concerning the risks and/or benefits associated with Inferior Vena Cava Filter(s), including but not limited to the Bard Inferior Vena Cava Filter implanted in you.
- (i) Not applicable
- (ii) The documents are attached        [OR] I have no documents   X
- (m) Produce any and all documents reflecting the model number and lot number of the Bard Inferior Vena Cava Filter(s) you received.
- (i) Not applicable
- (ii) The documents are attached   X   [OR] I have no documents
- (n) If you underwent surgery or any other procedure to remove, in whole or in part, the Bard Inferior Vena Cava Filter(s), produce any and all documents, other than documents that may have been generated by expert witnesses retained by your

counsel for litigation purposes, that relate to any evaluation of the Bard Inferior Vena Cava Filter(s) removed from you.

- (i) Not applicable\_\_\_\_\_
- (ii) The documents are attached   X   [OR] I have no documents\_\_\_\_\_
- (o) If you claim lost wages or lost earning capacity, produce copies of your Federal and State tax returns for the five (5) years prior to implantation of the Bard Inferior Vena Cava Filter(s) to the present redacting irrelevant information.
  - (i) Not applicable   X
  - (ii) The documents are attached\_\_\_\_\_ [OR] I have no documents\_\_\_\_\_
- (p) Produce all documents in your possession, custody, or control concerning payment by Medicare on behalf of the injured party and relating to the injuries claimed in this lawsuit. This includes, but is not limited to Interim Conditional Payment summaries and/or estimates prepared by Medicare or its representatives regarding payments made on your behalf for medical expenses relating to the subject of this litigation.
  - (i) Not applicable\_\_\_\_\_


**Medical bills have been requested and will be provided.**

- (ii) The documents are attached\_\_\_\_\_ [OR] I have no documents   X

*[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]*

- (q) Produce all screenshots of all webpages of each type of social media used by you (including, but not limited to, Facebook, Twitter, Instagram, Vine, Snapchat, YouTube, LinkedIn) showing any and all “posts” and/or “messages” from the date of implantation to the present.
  - (i) Not applicable   X
  - (ii) The documents are attached\_\_\_\_\_ [OR] I have no documents\_\_\_\_\_
- (r) Produce the Bard Inferior Vena Cava Filter(s) or any and all components thereof previously implanted in you.  
Not Applicable

VERIFICATION

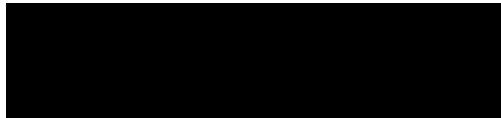
I, , declare under penalty of perjury, subject to all applicable laws and in the presence of the below named witness, that I have carefully reviewed the final copy of this Plaintiff Fact Sheet dated 7-21-16 and verified that all of the information provided is true and correct to the best of my knowledge, information and belief.

Deanna Porter

Signature of Witness

Deanna Porter

Name of Witness



**REDACTED DOCUMENTS RELATED  
TO DOCKET 8186**

**Exhibit M-I - REDACTED**

Do Not Disclose - Subject to Further Confidentiality Review

1 UNITED STATES DISTRICT COURT  
DISTRICT OF ARIZONA

2 No. MD-15-02641-PHX-DGC

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4 In Re: Bard IVC Filters Products  
Liability Litigation

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DO NOT DISCLOSE - SUBJECT TO FURTHER  
6 CONFIDENTIALITY REVIEW

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WITNESS: 

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9 Pursuant to Fed. R. Civ. P. 26 and 30  
10 the videotaped deposition of Pho M. Nguyen, M.D.  
11 was taken before Janine N. Leroux, Stenographic  
12 Court Reporter and Notary Public - Special  
13 Commission in and for the State of Kentucky at  
14 Large, at Kings Daughter's Medical Center  
15 located at 2201 Lexington Avenue, Ashland,  
16 Kentucky on Thursday, June 1st, 2017, commencing  
17 at the approximate hour of 8:19 a.m. Said  
18 deposition was taken pursuant to Notice.

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1 Q And if you would, would you explain  
2 actually the anatomy of the inferior vena cava,  
3 what is that?

4 A The inferior vena cava it's a large  
5 vein. It's a confluence of veins that drain back  
6 to the heart from your lower extremity inferiorly,  
7 go back towards the heart.

8 Q Are you currently placing IVC filters?

9 A Yes.

10 Q How often do you place those?

11 A Not as often as we used to but once or  
12 twice a month.

13 Q And for what reasons?

14 A Here at King's Daughters Medical Center  
15 we work a lot with the cancer patients, so  
16 patients who have high hypercoagulable state  
17 typically include cancer patients.

18 Patients who have recent trauma or  
19 recent orthopedic surgery that's going to be  
20 immobilized that have high risk for deep venous  
21 thrombosis, specifically from the lower extremity,  
22 a patient who cannot be on anti-coagulation that  
23 needs to be prophylactically put on an IVC filter.

24 Q When you -- when did you first start  
25 placing IVC filters? And when we talk about IVC



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1 filters, we're talking about filters that go into  
2 the inferior vena cava, the large vein of the  
3 body, correct?

4 A Yes.

5 Q When did you start?

6 A During my training at the University of  
7 Tennessee in Knoxville first year residency, I  
8 assisted my attending physician to place those  
9 during my training, and then continue through my  
10 residency at University of Cincinnati and also my  
11 fellowship.

12 Q Have you placed permanent filters?

13 A I have placed less than five permanent  
14 filters.

15 Q And the other filters that you've  
16 placed are what are known as optional filters or  
17 retrievable?

18 A They're called retrievable filters,  
19 that's correct.

20 Q How many of those have you placed?

21 A I do not know the exact number. I  
22 think definitely more than 50 and less than --  
23 less than 300, I guess.

24 Q And back in 2012, what type of filters  
25 were you placing, do you remember?

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1           A       2012. I think at King's Daughters we  
2       have -- there are several filters they have  
3       available for us to use.

4                   I think we have -- I'm not sure at that  
5       time. The Bard have like G2® or is it ECLIPSE™?  
6       I'm not sure what was the name of the filter. We  
7       also have Gunther Tulip®. We also have -- I think  
8       we still have the Optease®, and we have like  
9       several others, but those are the more common ones  
10      that's available at that time.

11          Q       Have you ever placed an ECLIPSE™ filter  
12      that's made by Bard?

13          A       Yes. Now, I may get confused because  
14      that generation of Bard filters they changed the  
15      name, so I have placed Bard filters I think during  
16      my residency fellowship from G2® to -- I'm sorry,  
17      from Recovery to G2® to ECLIPSE™ and another  
18      filter that's from Bard. I also place some other  
19      filter, also.

20          Q       [REDACTED]  
[REDACTED] [REDACTED] [REDACTED]  
[REDACTED] [REDACTED]

23          A       [REDACTED]

24          Q       And is that consistent with your  
25      medical record?

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1 A Yes.

2 Q [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 A [REDACTED]

6 Q In that period of time, how many -- how  
7 often were you removing filters?

8 A Again, I don't remember the exact  
9 number, more than 50. I don't know the exact  
10 number.

11 Q And again, those filters range with the  
12 different product lines that you just mentioned?

13 A That's correct.

14 Q And when you talk about a retrievable  
15 filter, what do you mean by that?

16 A A retrievable filter is a filter that  
17 you can place temporarily and give a patient a  
18 chance to get over an episode where they need to  
19 have a filter to prophylactically or be able to  
20 catch all the clots because they have high risk of  
21 deep venous thrombosis from their lower extremity.

22 Once they are back to their normal  
23 activity when they are no longer in need of an IVC  
24 filter, then you can go inside the inferior vena  
25 cava and try to retrieve or take the IVC filter

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1 out.

2 Q And in terms of the Bard line of  
3 filters, they were implanted how, through the  
4 femoral or the jugular?

5 A Yes, you can go either way.

6 Q And -- and the way that they were  
7 implanted -- and when we talk about the femoral  
8 approach or the jugular approach -- first of all,  
9 let's talk about the femoral approach.

10 If you'll explain to the jury what is  
11 that?

12 A Femoral approach is the patient is  
13 lying in a supine position. I typically use an  
14 ultrasound machine and take a look and make sure  
15 the left or right femoral veins are open. And if  
16 they are open, we'll use a sterile technique. We  
17 get access under ultrasound guide and using a  
18 micropuncture set.

19 Once we get inside the vein, we dial it  
20 up to a 5 French Catheter Micro Access Kit. We  
21 inject contrast, make sure everything is open, and  
22 put the wire in and that's how you get the access.

23 Q And then the jugular?

24 A Similar concept. We'll ultrasound the  
25 right neck. Typically I like to go in the right

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

9 Q Have you referred other patients whose  
10 filters you could not remove to other facilities  
11 for a removal attempt?

12 A No.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

25 Q I want to clarify back in -- I got